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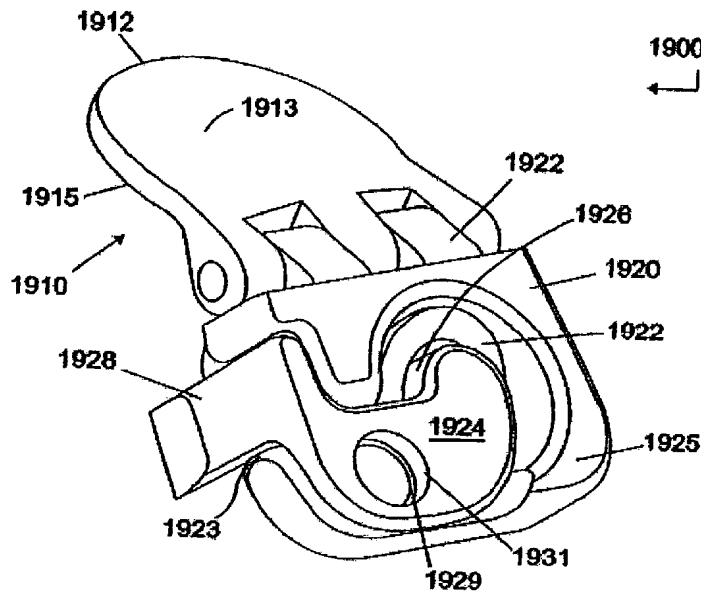
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[Continued on next page]

(54) Title: INTER-FACET IMPLANT



(57) Abstract: Systems and method in accordance with the embodiments of the present invention can include an implant (1900) for positioning within a facet joint for distracting the spine, thereby increasing the area of the canals and openings through which the spinal cord and nerves must pass, and decreasing pressure on the spinal cord and/or nerve roots. The implant (1900) can be inserted laterally or posteriorly.



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INTER-FACET IMPLANT**CLAIM OF PRIORITY**

5 This application claims priority to the following applications, which are all incorporated herein by reference:

United States Provisional Application No. 60/635,453 entitled INTER-CERVICAL FACET IMPLANT AND METHOD, by James F. Zucherman *et al.*, filed December 13, 2004 (Attorney Docket
10 No. KLYC-01118US0);

United States Provisional Application No. 60/668,053 entitled INTER-CERVICAL FACET IMPLANT DISTRACTION TOOL, by Scott A. Yerby *et al.*, filed April 4, 2005 (Attorney Docket No. KLYC-01125US0);

United States Provisional Application No. 60/679,363 entitled INTER-CERVICAL FACET
15 IMPLANT WITH IMPLANTATION TOOL, by Charles J. Winslow *et al.*, filed May 10, 2005 (Attorney Docket No. KLYC-01118US7);

United States Provisional Application No. 60/679,361 entitled INTER-CERVICAL FACET IMPLANT WITH IMPLANTATION TOOL, by Charles J. Winslow *et al.*, filed May 10, 2005; (Attorney Docket No. KLYC-01118US8);

20 United States Provisional Application No. 60/679,377 entitled INTER-CERVICAL FACET IMPLANT WITH IMPLANTATION TOOL, by Charles J. Winslow *et al.*, filed May 10, 2005 (Attorney Docket No. KLYC-01118US9);

United States Provisional Application No. 60/687,765 entitled INTER-CERVICAL FACET IMPLANT WITH MULTIPLE DIRECTION ARTICULATION JOINT AND METHOD FOR
25 IMPLANTING, by James F. Zucherman *et al.*, filed June 6, 2005 (KLYC-01118US6);

United States Provisional Application No. 60/717,369 entitled INTER-CERVICAL FACET IMPLANT WITH SURFACE ENHANCEMENTS, by James F. Zucherman *et al.*, filed September 15, 2005; (Attorney Docket No. KLYC-01133US0);

United States Utility Patent Application No. 11/053,399 entitled INTER-CERVICAL FACET
30 IMPLANT AND METHOD, by Charles J. Winslow *et al.*, filed February 8, 2005 (Attorney Docket No. KLYC-01118US1);

United States Utility Patent Application No. 11/053,624 entitled INTER-CERVICAL FACET IMPLANT AND METHOD, by Charles J. Winslow *et al.*, filed February 8, 2005 (Attorney Docket No. KLYC-01118US2);

United States Utility Patent Application No. 11/053,735 entitled INTER-CERVICAL FACET IMPLANT AND METHOD, by Charles J. Winslow *et al.*, filed February 8, 2005 (Attorney Docket No. KLYC-01118US3);

United States Utility Patent Application No. 11/053,346 entitled INTER-CERVICAL FACET IMPLANT AND METHOD, by Charles J. Winslow *et al.*, filed February 8, 2005 (Attorney Docket No. KLYC-01122US0);

United States Utility Patent Application No. 11/093,557 entitled INTER-CERVICAL FACET IMPLANT WITH LOCKING SCREW AND METHOD, by Charles J. Winslow *et al.*, filed March 30, 2005 (KLYC-01118US5); and

United States Utility Patent Application No. 11/093,689 entitled INTER-CERVICAL FACET IMPLANT AND METHOD FOR PRESERVING THE TISSUES SURROUNDING THE FACET JOINT, by Carl Laurysen *et al.*, filed March 30, 2005 (KLYC-01124US0).

TECHNICAL FIELD

This invention relates to interspinous process implants.

BACKGROUND OF THE INVENTION

The spinal column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example only, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), and facet arthropathy. Spinal stenosis results in a reduction foraminal area (i.e., the available space for the passage of nerves and blood vessels) which compresses the cervical nerve roots and causes radicular pain. Humphreys, S.C. et al., *Flexion and traction effect on C5-C6 foraminal space*, Arch. Phys. Med. Rehabil., vol. 79 at 1105 (Sept. 1998). Another symptom of spinal stenosis is myelopathy, which results in neck pain and muscle weakness. Id. Extension and ipsilateral rotation of the neck further reduces the foraminal area and contributes to pain, nerve root compression, and neural injury. Id.; Yoo, J.U. et al., *Effect of cervical spine motion on the neuroforaminal dimensions of human cervical spine*, Spine, vol. 17 at 1131 (Nov. 10, 1992). In contrast, neck flexion increases the foraminal area. Humphreys, S.C. et al., *supra*, at 1105.

In particular, cervical radiculopathy secondary to disc herniation and cervical spondylotic

foraminal stenosis typically affects patients in their fourth and fifth decade, and has an annual incidence rate of 83.2 per 100,000 people (based on 1994 information). Cervical radiculopathy is typically treated surgically with either an anterior cervical discectomy and fusion (“ACDF”) or posterior laminoforaminotomy (“PLD”), with or without facetectomy. ACDF is the most commonly performed surgical procedure for cervical radiculopathy, as it has been shown to increase significantly the foramina dimensions when compared to a PLF.

It is desirable to eliminate the need for major surgery for all individuals, and in particular, for the elderly. Accordingly, a need exists to develop spine implants that alleviate pain caused by spinal stenosis and other such conditions caused by damage to, or degeneration of, the cervical spine.

The present invention addresses this need with implants and methods for implanting an apparatus into at least one facet joint of the cervical spine to distract the cervical spine while preferably preserving mobility and normal lordotic curvature.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a lateral view of two adjacent cervical vertebrae and spinous processes, highlighting the cervical facet joint.

FIG. 2 depicts a lateral view of the cervical spine with spinal stenosis.

FIG. 3A depicts correction of cervical stenosis or other ailment with a wedge-shaped embodiment of the implant of the invention positioned in the cervical facet joint.

FIG. 3B depicts correction of cervical kyphosis or loss of lordosis with a wedge-shaped embodiment of the invention with the wedge positioned in the opposite direction as that depicted in **FIG. 3A**.

FIG. 4 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention including a screw fixation device for attaching to a single vertebra.

FIG. 5 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising screw fixation of two implants, one implant fixed to each of two adjacent vertebrae.

FIG. 6 shows cervical spine kyphosis, or loss of lordosis.

FIG. 7 shows correction of cervical kyphosis, or loss of lordosis, with a further embodiment of the implant of the invention comprising two facet implants with screw fixation.

FIG. 8 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising a facet implant and a keel.

FIG. 9 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising facet implant, a keel, and screw fixation.

FIG. 10 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising a facet implant with teeth.

FIG. 11 depicts correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising a facet implant with teeth and screw fixation.

5 **FIG. 12** depicts correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet implants having bony ingrowth surfaces.

FIG. 13 depicts correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet implants having bony ingrowth surfaces and posterior alignment guide.

10 **FIG. 14** shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet implants with increased facet joint contact surfaces.

FIG. 15 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet implants having bony ingrowth surfaces and screw fixation.

15 **FIG. 16** shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet implants with articular inner surfaces.

FIG. 17 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising a facet joint implant with a roller.

FIG. 18 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising a facet joint implant with a plurality of rollers.

20 **FIG. 19** shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet joint implants, screw fixation, and elastic restraint.

FIG. 20 shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet joint implants, screw fixation, and spring restraint.

25 **FIG. 21** shows correction of cervical stenosis or other ailment with a further embodiment of the implant of the invention, comprising two facet joint implants, screw fixation, and magnetic restraint.

FIG. 22A shows a perspective view of a further embodiment of implant of the invention.

FIG. 22B shows a perspective exploded view of the embodiment of the invention shown in **FIG. 22A**.

30 **FIG. 23A** depicts a posterior view of the embodiment of the implant of the invention shown in **FIG. 22A**.

FIG. 23B shows a posterior view of a locking plate of the embodiment of the implant of the invention shown in **FIG. 22A**.

FIG. 24A depicts a lateral side view of the embodiment of the implant of the invention shown in **FIG. 22A**.

FIG. 24B shows a lateral side view of the keel of the locking plate of the embodiment of the implant of the invention shown in **FIG. 22A**.

FIG. 25A shows a perspective view of a further embodiment of the implant of the invention.

FIG. 25B shows a side view of the embodiment of the implant of the invention in **FIG. 25A**,
5 having a curved, uniformly-thick **artificial facet joint spacer or inter-facet spacer** including a tapered end

FIG. 26A shows a perspective view of a further embodiment of the implant of the invention having a locking cam in a first position.

FIG. 26B shows a posterior view of the embodiment of the implant of the invention depicted in **FIG. 26A**.

10 **FIG. 27A** depicts a side view of the embodiment of the implant of the invention shown in **FIGS. 26A and 26B**, implanted in the cervical spine.

FIG. 27B shows a posterior perspective view of the embodiment of the implant of the invention shown in **FIGS. 26A, 26B**, and **FIG. 27A**.

FIG. 28A depicts a posterior perspective view of a further embodiment of the implant of the
15 invention.

FIG. 28B depicts a side view of the embodiment of the implant of the invention shown in **FIG. 28A**.

FIG. 29A depicts a side view of an embodiment of a sizing tool of the invention.

FIG. 29B depicts a top view of an embodiment of the sizing tool of the invention depicted in **FIG. 29A**.
20 **29A**.

FIG. 29C depicts a perspective view of an embodiment of the sizing tool of the invention depicted in **FIGS. 29A and 29B**.

FIG 29D depicts a side view of the head of the sizing tool of the invention depicted in **FIG. 29A**.

FIG. 29E depicts a cross-sectional view of the head of the sizing tool of the invention depicted in
25 **FIGS. 29A-29C**.

FIG. 30 is a flow diagram of an embodiment of a method of the invention.

FIG. 31A is posterior view of a further embodiment of the implant of the invention.

FIG. 31B is a side view of an embodiment of a locking screw of the implant of the invention depicted in **FIG. 31A**.

30 **FIG. 32** is a posterior view of a further embodiment of the implant of the invention.

FIGS. 33A and 33B depict initial and final insertion positions of the embodiment of the invention depicted in **FIG 32**.

FIGS. 34A and 34B illustrate a top and bottom plan view of an alternative embodiment of an

inter-cervical facet implant in accordance with the present invention.

FIG. 35 is a partially exploded perspective view of the implant of **FIGs. 34A** and **34B**.

FIGs. 36A and **36B** illustrate side views of the implant of **FIGs. 34A** and **34B** illustrating a general range of motion of the implant.

5 **FIG. 37** is a side view of still another embodiment of an implant in accordance with the present invention.

FIG. 38 is a flow diagram of an embodiment of a method in accordance with the present invention.

FIG. 39A is a posterior view of a further embodiment of the implant of the invention.

FIG. 39B is a side view of a further embodiment of the implant of the invention.

10 **FIG. 40A** is a perspective view of an embodiment of the implantation tool of the invention.

FIG. 40B is a perspective view of the engagement head of the implantation tool of the invention.

FIG. 41A shows a perspective view of a further embodiment of the implant of the invention having a locking cam in a first position.

15 **FIG. 41B** shows a perspective view of a further embodiment of the implant of the invention having a locking cam in a second position.

FIG. 42A is a side view of still another embodiment of an implant in accordance with the present invention.

FIG. 42B is a top view of the implant of **FIG. 42A**.

20 **FIG. 42C** is a bottom view of the implant of **FIG. 42A**.

FIG. 42D-F are side views of the implant of **FIG. 42A** illustrating the various arrangements of a bone screw associated the implant.

FIG. 42G is an end view of the implant of **FIG. 42F** illustrating the arrangement of the bone screw associated the implant from an alternative viewing angle.

25 **FIG. 43** is a side view of still another embodiment of an implant in accordance with the present invention.

FIG. 44 illustrates a side view of a distraction tool in accordance with one embodiment of the present invention.

30 **FIG. 45** illustrates a side view of the distraction tool in accordance with one embodiment of the present invention.

FIG. 46A illustrates a perspective view of a distraction head of the distraction tool in accordance with one embodiment of the present invention.

FIG. 46B illustrates a perspective view of the distraction head of the distraction tool in accordance with one embodiment of the present invention.

FIG. 47A illustrates a side view of a curved distraction head of the distraction tool in accordance with one embodiment of the present invention.

FIG. 47B illustrates a side view of the curved distraction head of the distraction tool in accordance with one embodiment of the present invention.

5 **FIG. 48A** illustrates a perspective view of a distraction tool in accordance with one embodiment of the present invention.

FIG. 48B illustrates a top view of the distraction tool in accordance with one embodiment of the present invention.

10 **FIGs. 49A-49C** illustrate one distraction process using the distraction tool of the present invention.

FIG. 49D illustrates a flow chart of one implantation method in accordance with one embodiment of the present invention.

FIG. 50A illustrates a perspective view of a distraction and insertion tool in accordance with one embodiment of the present invention.

15 **FIG. 50B** illustrates a top view of the distraction and insertion tool shown in **FIG. 50A** in accordance with one embodiment of the present invention.

FIG. 51 illustrates a perspective view of a distraction tool with sizing mechanism in accordance with one embodiment of the present invention.

20 **Detailed Description**

Embodiments of the present invention provide for a minimally invasive surgical implantation method and apparatus for cervical spine implants that preserves the physiology of the spine. In particular, embodiments provide for distracting the cervical spine to increase the foraminal dimension in extension and neutral positions. Such implants, when implanted in the cervical facet joints, distract, or increase the
25 space between, the vertebrae to increase the foraminal area or dimension, and reduce pressure on the nerves and blood vessels of the cervical spine.

The facet joints in the spine are formed between two vertebrae as follows. Each vertebra has four posterior articulating surfaces: two superior facets and two inferior facets, with a superior facet from a lower vertebra and an inferior facet of an upper vertebra forming a facet joint on each lateral side of the
30 spine. In the cervical spine, the upward inclination of the superior articular surfaces of the facet joints allows for considerable flexion and extension, as well as for lateral mobility. Each facet joint is covered by a dense, elastic articular capsule, which is attached just beyond the margins of the articular facets. The capsule is larger and looser in the cervical spine than in the thoracic and lumbar spine. The inside of the capsule is lined by a synovial membrane which secretes synovial fluid for lubricating the facet joint. The

exterior of the joint capsule is surrounded by a capsular ligament. It is this ligament and the joint capsule that must be cut in the embodiments of the method described herein for inserting the artificial facet joint spacer or inter-facet spacer.

In a specific preferred embodiment, an implanted interfacet spacer of 1.5 mm to 2.5 mm in width can result in interfacet distraction that increases foraminal dimension in extension and neutral. Other interfacet spacer dimensions also are contemplated by the invention described herein below. The present embodiments also preserve mobility of the facet joints.

Further embodiments of the present invention accommodate the distinct anatomical structures of the spine, minimize further trauma to the spine, and obviate the need for invasive methods of surgical implantation. Embodiments of the present invention also address spinal conditions that are exacerbated by spinal extension.

FIG. 1 shows a simplified diagram of a portion of the cervical spine, focusing on a cervical facet joint **1** formed between two adjacent cervical vertebrae. The spinous processes **3** are located posteriorly and the vertebral bodies **5** are located anteriorly, and a nerve root canal **7** is visible. Each vertebra has four posterior articulating surfaces: two superior facets and two inferior facets, with a superior facet from a lower vertebra and an inferior facet of an upper vertebra forming a facet joint on each lateral side of the spine. In the cervical spine, the upward inclination of the superior articular surfaces of the facet joints allows for considerable flexion and extension, as well as for lateral mobility. Each facet joint is covered by a dense, elastic articular capsule, which is attached just beyond the margins of the articular facets. The capsule is large and looser in the cervical spine than in the thoracic and lumbar spine. The inside of the capsule is lined by a synovial membrane which secretes synovial fluid for lubricating the facet joint. The exterior of the joint capsule is surrounded by a capsular ligament. It is this ligament that may be pushed out of the way in the embodiments of the method for inserting the facet joint spacer or inter-facet spacer, described herein.

FIG. 2 depicts cervical foraminal stenosis. From the drawing, the nerve root canal **7** is narrowed relative to the nerve root canal **7** depicted in **FIG. 1**. The spinal canal and/or intervertebral foramina also can be narrowed by stenosis. The narrowing can cause compression of the spinal cord and nerve roots.

FIG. 3A shows a first embodiment **100** of the present invention, which is meant to distract at least one facet joint, in order to increase the dimension of the neural foramen while retaining facet joint mobility. The wedge-shaped embodiment or inter-facet spacer **100** is a wedge-shaped implant that can be positioned in the cervical facet joint **101** to distract the joint and reverse narrowing of the nerve root canal **107**. In this embodiment or inter-facet spacer **100**, the implant is positioned with the narrow portion of the wedge facing anteriorly. However, it is also within the scope of the present invention to position embodiment or inter-facet spacer **100** (**FIG. 3B**) with the wide portion of the wedge facing anteriorly, to

correct for cervical kyphosis or loss of cervical lordosis.

Referring to **FIG. 4**, the embodiment **200** of the implant has a joint insert or inter-facet spacer **210**, also herein referred to as a facet joint spacer or inter-facet spacer, that is positioned in the cervical facet joint **101**. The joint insert or inter-facet spacer **210** can be wedge-shaped with the narrow part of the wedge facing anteriorly. Alternatively, the joint insert or inter-facet spacer **210** need not be wedge-shaped but can be of substantially uniform thickness, the thickness determined by an individual patient's need for distraction of the cervical facet joint **201**. As with embodiment **100**, one objective of this embodiment is facet joint distraction, and joint mobility after implantation. The joint insert or inter-facet spacer **210** is continuous with a posterior sheath **220** bent at an angle from the joint insert or inter-facet spacer **210** to align substantially parallel with the bone. The posterior sheath can lie against the lamina, preferably against the lateral mass. The posterior sheath **220** can have a bore **230** which can accept a bone screw **240**. Alternatively, the bore **230** can accept any other appropriate and/or equivalent fixation device capable of fixing the embodiment **200** to the spine. The device is thereby affixed to the vertebra, preferably by fixing to the lateral mass.

FIG. 5 shows embodiment **300**, which is the use of two embodiments **200**, each fixed to one of two adjacent cervical vertebrae. As with embodiment **200**, the implanted facet joint is distracted and joint mobility is retained. A joint insert or inter-facet spacer **310** from each of the two implants is inserted and positioned in the cervical facet joint **301**. In this embodiment, the joint inserts or inter-facet spacers **310** are substantially flat and parallel to each other and are not wedge-shaped. Alternatively, the joint inserts or inter-facet spacers **310** can together define a wedge-shaped insert that is appropriate for the patient. The two joint inserts or inter-facet spacers **310** combined can have, by way of example, the shape of the joint insert or inter-facet spacer **210** in **FIG. 4**. Embodiment **300** then can be fixed to the spine with a screw **340** or any other appropriate fixation device, inserted through a bore **330** in the posterior sheath **320**. The posterior sheath **320** can be threaded to accept a screw. The screw can be embedded in the lamina, preferably in the lateral mass, where possible.

It is within the scope of the present invention to use and/or modify the implants of the invention to correct cervical spine kyphosis, or loss of lordosis. **FIG. 6** depicts a cervical spine lordosis. **FIG. 7** demonstrates an embodiment **400** which contemplates positioning two implants to correct for this spinal abnormality while retaining facet joint mobility. The joint insert or inter-facet spacer **410** of each implant is shaped so that it is thicker at its anterior portion. Alternatively, the implants can be shaped to be thicker at the posterior ends, for example as depicted in **FIG. 3A**. The posterior sheath **420** of each implant is bent at an angle from the joint insert or inter-facet spacer **410** to be positioned adjacent to the lateral mass and/or lamina, and has a bore **430** to accept a screw **440** or other appropriate and/or equivalent fixation means to

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fix the embodiment **400** to the spine, preferably to the lateral mass. The placement of two joint inserts or inter-facet spacers **410** in the cervical facet joint **401** distracts the facet joint, which shifts and maintains the vertebrae into a more anatomical position to preserve the physiology of the spine.

FIG. 8 shows a further embodiment **500** of the implant of the invention, wherein the joint insert or inter-facet spacer **510** has a keel **550** on an underside of the joint insert or inter-facet spacer **510**. The keel **550** can be made of the same material or materials set forth above. The surfaces of the keel **550** can be roughened in order to promote bone ingrowth to stabilize and fix the implant **500**. In other embodiments, the keel **550** can be coated with materials that promote bone growth such as, for example, bone morphogenic protein (“BMP”), or structural materials such as hyaluronic acid “HA,” or other substances which promote growth of bone relative to and into the keel **550**.

The keel **550** can be embedded in the facet bone, to facilitate implant retention. The keel **550** can be placed into a channel in the facet bone. The channel can be pre-cut. Teeth (not shown), preferably positioned posteriorly, also may be formed on the keel **550** for facilitating retention of the implant **500** in the cervical facet joint **501**. As noted above, the joint insert or inter-facet spacer **510** can be substantially flat or wedge-shaped, depending upon the type of distraction needed, i.e., whether distraction is also necessary to correct abnormal curvature or lack of curvature in the cervical spine. Because the joint is not fused, mobility is retained, as with the embodiments described above and herein below.

FIG. 9 illustrates that a further embodiment **600** of the implant of the invention can have both screw fixation and a keel **650** for stability and retention of the implant **600**. On embodiment **600**, the joint insert or inter-facet spacer **610** is continuous with a posterior sheath **620** having a bore hole **630** to accept a screw **640** which passes through the bore **630** and into the bone of the vertebrae, preferably into the lateral mass, or the lamina. The bore **630** can be threaded or not threaded where it is to accept a threaded screw or equivalent device. Alternatively, the bore **630** need not be threaded to accept a non-threaded equivalent device. The keel **650** is connected with the joint insert or inter-facet spacer **610** and embeds in the bone of the cervical facet joint **601** to promote implant retention.

A further alternative embodiment **700** is illustrated in **FIG. 10**. In this embodiment **700**, the joint insert or inter-facet spacer **710** has on a lower side at least one tooth **760**. It should be clear to one of ordinary skill in the art that a plurality of teeth **760** is preferable. The teeth **760** are able to embed in the bone of the cervical facet joint **701** to facilitate retention of the implant **700** in the joint **701**. The teeth **760** can face in a direction substantially opposite the direction of insertion, for retention of the implant **700**. As above, the joint insert or inter-facet spacer **710** can be wedge-shaped or substantially even in thickness, depending upon the desired distraction. Because the implant distracts and is retained without fusion, facet joint mobility is retained.

FIG. 11 depicts a further embodiment **800** of the implant of the invention. In this embodiment **800**, the joint insert or inter-facet spacer **810** is continuous with a posterior sheath **820** having a bore **830** for accepting a fixation device **840**, as described above. The fixation device **840** can be a screw which fits into a threaded bore **830**; alternatively, the fixation device **830** can be any other compatible and appropriate device. This embodiment **800** further combines at least one tooth **860** on an underside of the joint insert or inter-facet spacer **810** with the posterior sheath **820**, bore **830** and fixation device **840** to address fixation of the implant **800** in a cervical facet joint **801**. It will be recognized by one of ordinary skill in the art that the implant **800** can have a plurality of teeth **860** on the underside of the joint insert or inter-facet spacer **810**.

FIG. 12 shows yet another embodiment **900** of an implant of the present invention. In this embodiment **900**, the joint inserts or inter-facet spacers **910** of two implants **900** are positioned in a cervical facet joint **901**. As described above, the joint inserts or inter-facet spacers **910** can be wedge-shaped as needed to restore anatomical curvature of the cervical spine and to distract, or the joint inserts or inter-facet spacers **910** can be of substantially uniform thickness. The implants **900** each comprise a joint insert or inter-facet spacer **910** with an outer surface **970** that interacts with the bone of the cervical facet joint **901**. On the upper implant **900**, the surface **970** that interacts with the bone is the upper surface **970** and on the lower implant **900**, the surface **970** that interacts with the bone is the lower surface **970**. Each surface **970** can comprise a bone ingrowth surface **980** to create a porous surface and thereby promote bone ingrowth and fixation. One such treatment can be with plasma spray titanium, and another, with a coating of sintered beads. Alternatively, the implant **900** can have casted porous surfaces **970**, where the porous surface is integral to the implant **900**. As a further alternative, the surfaces **970** can be roughened in order to promote bone ingrowth into these defined surfaces of the implants **900**. In other embodiments, the surfaces **970** can be coated with materials that promote bone growth such as for example bone morphogenic protein ("BMP"), or structural materials such as hyaluronic acid ("HA"), or other substances which promote growth of bone on other external surfaces **970** of the implant **900**. These measures facilitate fixation of the implants **900** in the facet joint, but do not result in fusion of the joint, thereby retaining facet joint mobility, while also accomplishing distraction of the joint.

FIG. 13 depicts yet another embodiment **1000** of the implant of the present invention. In this embodiment **1000**, the joint inserts or inter-facet spacers **1010** of two implants **1000** are positioned in a cervical facet joint **1001**. As described above, the joint inserts or inter-facet spacers **1010** can be wedge-shaped as needed to restore anatomical curvature of the cervical spine and to distract, or the joint inserts or inter-facet spacers **1010** can be of substantially uniform thickness. The implants **1000** each comprise a joint insert or inter-facet spacer **1010** with an outer surface **1070** that interacts with the bone of the cervical

facet joint **1001**. On the upper implant **1000**, the surface **1070** that interacts with the bone is the upper surface and on the lower implant **1000**, the surface **1070** that interacts with the bone is the lower surface. As set forth above, each outer surface **1070** can comprise a bone ingrowth surface **1080** to create a porous surface and thereby promote bone ingrowth and fixation, without facet joint fusion and loss of mobility. In one preferred embodiment, the bone ingrowth surface **1080** can be created with plasma spray titanium, and/or with a coating of sintered beads. In an alternative preferred embodiment, the implant **1000** can have casted porous surfaces **1070**, where the porous surface is integral to the implant **1000**. In a further alternative preferred embodiment, the surfaces **1070** can be roughened in order to promote bone ingrowth into these defined surfaces of the implants **1000**. In other preferred embodiments, the surfaces **1070** can be coated with materials that promote bone growth such as for example BMP, or structural materials such as HA, or other substances which promote growth of bone on other external surfaces **1070** of the implant **1000**.

The implant **1000** can have a posterior alignment guide **1090**. The posterior alignment guides **1090** of each implant **1000** can be continuous with the joint inserts or inter-facet spacers **1010**. The posterior alignment guides substantially conform to the bone of the vertebrae when the joint inserts or inter-facet spacers **1010** are inserted into the cervical facet joint **1001**. The posterior alignment guides **1090** are used to align the implants **1000** so that the joint inserts or inter-facet spacers **1010** contact each other and not the bones of the cervical facet joint **1001** when the joint inserts or inter-facet spacers **1010** are positioned in the cervical facet joint **1001**.

FIG. 14 depicts a further embodiment **1100** of the implant of the present invention. In this embodiment **1100**, the joint inserts or inter-facet spacers **1110** of two implants **1100** are inserted into the cervical facet joint **1101**. Each of the joint inserts or inter-facet spacers **1110** is continuous with a cervical facet joint extender or facet-extending surface **1192**. The bone contacting surfaces **1170** of the joint inserts or inter-facet spacers **1110** are continuous with, and at an angle to, the bone contacting surfaces **1193** of the cervical facet joint extenders **1192**, so that the cervical facet joint extenders **1192** conform to the bones of the vertebrae exterior to the cervical facet joint **1101**. The conformity of the cervical facet joint extenders **1192** is achieved for example by forming the cervical facet joint extenders **1192** so that when the joint inserts **1110** are positioned, the cervical facet joint extenders **1192** curve around the bone outside the cervical facet joint **1101**.

The cervical facet joint extenders have a second surface **1184** that is continuous with the joint articular surfaces **1182** of the joint inserts or inter-facet spacers **1110**. The second surfaces **1184** extend the implant **1100** posteriorly to expand the joint articular surfaces **1182** and thereby to increase contact and stability of the spine at least in the region of the implants **1100**. It is to be understood that such facet joint

extenders **1192** can be added to the other embodiments of the invention described and depicted herein.

The embodiment depicted in **FIG. 15** shows two implants **1200** positioned in a cervical facet joint **1201**, having bony ingrowth surfaces as one preferred method of fixation, and using screws as another preferred method of fixation. In this embodiment, each of two implants **1200** has a joint insert or inter-facet spacer **1210** positioned in a cervical facet joint **1201**. As described above, the joint inserts or inter-facet spacers **1210** can be wedge-shaped as needed to restore anatomical curvature of the cervical spine and to distract, or the joint inserts or inter-facet spacers **1210** can be of substantially uniform thickness. The implants **1200** each comprise a joint insert or inter-facet spacer **1210** with an outer surface **1270** that interacts with the bone of the cervical facet joint **1001**. On the upper implant **1200**, the surface **1270** that interacts with the bone is the upper surface and on the lower implant **1200**, the surface **1270** that interacts with the bone is the lower surface. As set forth above, each outer surface **1270** can comprise a bone ingrowth surface **1280** to create a porous surface and thereby promote bone ingrowth and fixation. In one preferred embodiment, the bone ingrowth surface **1280** can be created with plasma spray titanium, and/or with a coating of sintered beads. In an alternative preferred embodiment, the implant **1200** can have casted porous surfaces **1270**, where the porous surface is integral to the implant **1200**. In a further alternative embodiment, the surfaces **1270** can be roughened in order to promote bone ingrowth into these defined surfaces of the implants **1200**. In other preferred embodiments, the surfaces **1270** can be coated with materials that promote bone growth such as for example BMP, or structural materials such as HA, or other substances which promote growth of bone on other external surfaces **1270** of the implant **1200**.

Screw fixation or other appropriate fixation also can be used with implants **1200** for fixation in the cervical facet joint **1201**. The joint insert or inter-facet spacer **1210** is continuous with a posterior sheath **1220** bent at an angle from the joint insert or inter-facet spacer **1210** to align substantially parallel with the bone, preferably the lateral mass or lamina. The posterior sheath **1220** can have a bore **1230** which can accept a bone screw **1240**, preferably into the lateral mass or lamina. Alternatively, the bore **1230** can accept any other appropriate and/or equivalent fixation means for fixing the embodiment **1200** to the spine.

FIG. 16 depicts a further preferred embodiment of the present invention. In this embodiment **1300**, two joint inserts or inter-facet spacers **1310** are positioned in the cervical facet joint **1301**. The joint inserts or inter-facet spacers each have outer surfaces **1370** that interact with the bone of the vertebrae forming the cervical facet joint. These outer surfaces **1370** of the embodiment **1300** can be treated to become bone ingrowth surfaces **1380**, which bone ingrowth surfaces **1380** contribute to stabilizing the two joint inserts or inter-facet spacers **1310** of the implant **1300**. In one preferred embodiment, the bone ingrowth surface **1380** can be created with plasma spray titanium, and/or with a coating of sintered beads.

In an alternative preferred embodiment, the implant **1300** can have casted porous surfaces **1370**, where the porous surface is integral to the implant **1300**. In a further alternative embodiment, the surfaces **1370** can be roughened in order to promote bone ingrowth into these defined surfaces of the implants **1300**. In other preferred embodiments, the surfaces **1370** can be coated with materials that promote bone growth such as for example BMP, or structural materials such as HA, or other substances which promote growth of bone on other external surfaces **1370** of the implant **1300**. This fixation stabilizes the implant **1300** in the facet joint without fusing the joint, and thus the implant preserves joint mobility, while accomplishing distraction and increasing foraminal dimension.

Also shown in **FIG. 16** are articular inner surfaces **1382** of the implants **1300**. These surfaces can be formed from a metal and polyethylene, the material allowing flexibility and providing for forward bending/flexion and backward extension of the cervical spine. The embodiment **1300** of **FIG. 16** can be made in at least two configurations. The first configuration includes a flexible spacer **1382** made, by way of example, using polyethylene or other suitable, flexible implant material. The flexible spacer **1382** can be permanently affixed to the upper and lower joint insert or inter-facet spacer **1310**. The spacer **1382** can be flat or wedge-shaped or have any other shape that would correct the curvature of the spine. In other configurations, the spacer **1382** can be affixed to only the upper insert **1310** or to only the lower insert **1310**. Alternatively, a spacer **1382** can be affixed to each of an upper insert **1310** and a lower insert **1310** with the upper insert **1310** and the lower insert **1310** being separate units.

FIG. 17 shows a further preferred embodiment of the implant of the present invention. In this embodiment **1400**, the implant has a roller **1496** mounted on a joint insert or inter-facet spacer **1410**, the roller being a further means of preserving joint mobility while accomplishing distraction. Both the roller **1496** and the joint insert or inter-facet spacer **1410** are positioned in the cervical facet joint **1401**. The joint insert or inter-facet spacer **1410** as in other embodiments has a bone-facing surface **1470** and joint articular surface **1482**. The bone-facing surface **1470** can interact with the lower bone of the cervical facet joint **1401**. Alternatively, the bone-facing surface can interact with the upper bone of the cervical facet joint **1401**. Between the bone-facing surface **1470** and the joint articular surface **1482** is an axis about which the roller **1496** can rotate. The roller **1496** rotates in a cavity in the joint insert or inter-facet spacer **1410**, and interacts with the top bone of the cervical facet joint **1401**. Alternatively, where the bone-facing surface **1470** of the joint insert or inter-facet spacer **1410** interacts with the top bone of the cervical facet joint **1401**, the roller **1496** rotates in a cavity in the joint insert or inter-facet spacer **1410** and interacts with the lower bone of the cervical facet joint **1401**. The rotation of the roller **1496** allows flexion and extension of the cervical spine. Alternatively, a roller such as roller **1496** can be secured to an upper and a lower insert such as inserts **410** in **FIG. 7**. As depicted in **FIG. 18**, a plurality of rollers **1496** also is possible.

FIG. 19 depicts a further embodiment of the implant of the present invention. In this embodiment, two implants **1500** are implanted in the cervical facet joint **1501**. Screw fixation or other appropriate fixation is used with implants **1500** for fixation in the cervical facet joint **1501**. The joint insert or inter-facet spacer **1510** is continuous with a posterior sheath **1520** bent at an angle from the joint insert or inter-facet spacer **1510** to align substantially parallel with the bone, preferably the lateral mass or lamina. The posterior sheath **1520** of each implant **1500** can have a bore **1530** which can accept a bone screw **1540**, preferably into the lateral mass or lamina. Alternatively, the bore **1530** can accept any other appropriate and/or equivalent fixation means for fixing the embodiment **1500** to the spine. The head of the screw **1540** in each posterior sheath **1520** of each implant **1500** has a groove **1598** or other mechanism for retaining an elastic band **1597**. The elastic band **1597** is looped around each of the two screws **1540** to restrain movement of the cervical spine without eliminating facet joint mobility. The band **1597** preferably can restrain flexion and lateral movement. The elastic band **1597** can be made of a biocompatible, flexible material.

FIG. 20 shows an alternative to use of an elastic band as in **FIG. 19**. In the embodiment in **FIG. 20**, the elastic band is replaced with a spring restraint **1699**, which extends between the heads of two screws **1640**, one screw fixing each of two implants **1600** in the cervical facet joint **1601**.

FIG. 21 shows another alternative to using an elastic band and/or a spring as in **FIGs. 19 or 20**. In **FIG. 21**, magnets **1795** is used for restraint between the two screws **1740**. The magnet **1795** can either be comprised of two opposing magnetic fields or two of the same magnetic fields to operate to restrain movement. The head of one of the two screws **1740** is magnetized, and the head of the other screw **1740** is magnetized with either the same or opposite field. If the magnets **1795** have the same polarity, the magnets **1795** repel each other and thus limit extension. If the magnets **1795** have opposite polarities, the magnets **1795** attract each other and thus limit flexion and lateral movement.

FIGs. 22A-24B, depict a further embodiment **1800** of the implant of the present invention. In this embodiment, a facet joint spacer (or insert) or inter-facet spacer (or insert) **1810** is connected with a lateral mass plate (also referred to herein as an anchoring plate) **1820** with a hinge **1822**. The hinge **1822** allows the lateral mass plate **1820** to bend at a wide range of angles relative to the facet joint spacer or inter-facet spacer and preferably at an angle of more than 90 degrees, and this flexibility facilitates positioning and insertion of the facet joint spacer or inter-facet spacer **1810** into a patient's facet joint, the anatomy of which can be highly variable among individuals. This characteristic also applies to embodiments described below, which have a hinge or which are otherwise enabled to bend by some equivalent structure or material property. The hinge **1822** further facilitates customizing the anchoring of the implant, i.e., the positioning of a fixation device. The hinge enables positioning of the lateral mass plate **1820** to conform to a patient's

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cervical spinal anatomy, and the lateral mass plate **1820** accepts a fixation device to penetrate the bone. The facet joint spacer or inter-facet joint spacer **1810** can be curved or rounded at a distal end **1812** (**FIG. 23A**), and convex or dome-shaped on a superior surface **1813** to approximate the shape of the bone inside the facet joint. The inferior surface **1815** can be flat or planar. Alternatively, the inferior surface **1815** can be concave. As another alternative, the inferior surface **1815** can be convex.

The lateral mass plate **1820**, when implanted in the spine, is positioned outside the facet joint, preferably against the lateral mass or against the lamina. The lateral mass plate **1820** has a bore **1830** therethrough. The bore **1830** can accept a bone screw **1840**, also referred to as a lateral mass screw, to secure the lateral mass plate **1820** preferably to the lateral mass or alternatively to another part of the spine, and thus to anchor the implant. The lateral mass screw **1840** preferably has a hexagonal head to accept an appropriately-shaped wrench. As described below, the head accepts a compatible probe **1826** from a locking plate **1824**.

The locking plate **1824** includes a keel **1828** with a wedge shaped distal end to anchor the implant, preferably in the lateral mass or in the lamina, outside the facet joint and to prevent rotation of the lateral mass plate **1820** and the locking plate **1824**. The keel **1828** aligns with a groove **1823** through an edge of the lateral mass plate **1820** to guide and align the keel **1828** as the keel **1828** cuts into a vertebra.

As noted above, the locking plate **1824** includes a probe **1826** that fits against the head of the lateral mass screw **1840**. The locking plate further includes a bore **1831** that can accept a machine screw (not shown) which passes through to an aligned bore **1829** in the lateral mass plate **1820** to hold the locking plate **1824** and the lateral mass plate **1820** together without rotational displacement relative to each other. The locking plate **1824** thus serves at least two functions: (1) maintaining the position of the lateral mass screw **1840** with the probe **1826**, so that the screw **1840** does not back out; and (2) preventing rotation of the implant with the keel **1828** and machine screw relative to the cervical vertebra or other vertebrae.

It is to be understood that other mechanisms can be used to lock the locking plate **1824** to the lateral mass plate **1820**. For example, the locking plate can include a probe with barbs that can be inserted into a port in the lateral mass plate. The barbs can become engaged in ribs that define the side walls of the port in the lateral mass plate

In the preferred embodiment depicted in **FIGs. 25A, 25B**, the lateral mass plate **1920** includes a recessed area **1922** for receiving the locking plate **1924** so that the locking plate **1924** is flush with the upper surface **1925** of the lateral mass plate **1920** when the probe **1926** is urged against the lateral mass screw **1940** and the keel **1928** is inserted into the lateral mass or the lamina of the vertebra. In the preferred embodiment depicted in **FIGs. 25A, 25B**, the shape and contours of the facet joint spacer or

inter-facet joint spacer **1910** can facilitate insertion of the facet joint spacer or inter-facet joint spacer **1910** into the cervical facet joint. In this embodiment, the facet joint spacer or inter-facet joint spacer **1910** has a rounded distal end **1912**. The distal end **1912** is tapered in thickness to facilitate insertion. The tapered distal end **1912** meets and is continuous with a proximal mid-section **1916** which, in this preferred embodiment, has a uniform thickness, and is connected flexibly, preferably with a hinge **1922**, to the lateral mass plate **1920**, as described above. The facet joint spacer (or insert) or inter-facet joint spacer (or insert) **1910**, with its proximal mid-section **1916** and tapered distal end **1912**, is curved downward, causing a superior surface **1913** of the facet joint spacer or inter-facet joint spacer **1910** to be curved. The curve can cause the superior surface **1913** to be convex, and the convexity can vary among different implants **1900** to suit the anatomical structure of the cervical facet joint(s) of a patient. An inferior surface **1915** accordingly can be preferably concave, flat, or convex. The curved shape of the implant can fit the shape of a cervical facet joint, which is comprised of an inferior facet of an upper vertebra and a superior facet of a lower adjacent vertebra. The convex shape of the superior surface **1913** of the facet joint spacer or inter-facet joint spacer **1910** fits with a concave shape of the inferior facet of the upper cervical vertebrae. The concave shape of the inferior surface **1915** of the facet joint spacer or inter-facet joint spacer **1910** fits with the convex shape of the superior facet of the cervical vertebrae. The degree of convexity and concavity of the facet joint spacer or inter-facet joint spacer inferior and superior surfaces can be varied to fit a patient's anatomy and the particular pairing of adjacent cervical vertebrae to be treated. For example, a less-curved facet joint spacer or inter-facet joint spacer **1910** can be used where the patient's cervical spinal anatomy is sized (as described below) and found to have less convexity and concavity of the articular facets. Generally for the same level the input for the right and left facet joint will be similarly shaped. It is expected that the similarity of shape of the facet joint spacer or inter-facet joint spacer and the smooth, flush surfaces will allow distraction of the facet joint without loss of mobility or damage to the bones of the cervical spine. Further, and preferably, the width of the mid-section **1916** is from 1.5 mm to 2.5 mm.

Except as otherwise noted above, the embodiment shown in **FIGs. 22A-24B** is similar to the embodiment shown in **FIGs. 25A, 25B**. Accordingly the remaining elements on the **1900** series of element numbers is preferably substantially similar to the described elements in the **1800** series of element numbers, as set forth above. Thus, by way of example, elements **1923, 1928, 1929** and **1930** are similar, respective elements **1823, 1828, 1829** and **1830**.

FIG. 30 is a flow chart of the method of insertion of an implant of the invention. The embodiment **1800** or **1900** of the present invention preferably is inserted in the following manner (only elements of the embodiment **1800** will be set forth herein, for purposes of the written description of a method of the invention). First the facet joint is accessed. A sizing tool **2200** (see **FIGs. 29A-C**) can be inserted to select

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the appropriate size of an implant of the invention for positioning in the cervical facet joint. This step may be repeated as necessary with, if desired, different sizes of the tool **2200** until the appropriate size is determined. This sizing step also distracts the facet joint and surrounding tissue in order to facilitate insertion of the implant. Then, the natural or artificial facet joint spacer or inter-facet joint spacer **1810** is urged between the facets into the facet joint. The facet itself is somewhat shaped like a ball and socket joint. Accordingly, in order to accommodate this shape, the spacer **1810** can have a rounded leading edge shaped like a wedge or tissue expander to cause distraction of the facet joint as the facet joint spacer or inter-facet joint spacer is urged into the facet joint of the spine. The natural or artificial facet joint spacer or inter-facet joint spacer **1810** also includes the convex surface **1813** in order to more fully accommodate the shape of the facet joint of the spine. However, as set forth above and as depicted in **FIG. 25B**, it is possible in the alternative to have a curve-shaped natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **1910** with a convex superior surface **1913** and a concave inferior surface **1915**, the distal end **1912** tapering to facilitate insertion, while the remainder of the natural or artificial facet joint spacer or inter-facet joint spacer **1910**, (i.e., the proximal section **1916**) has a uniform thickness.

Once the natural or artificial joint spacer **1810** is positioned, the lateral mass plate **1820** is pivoted downward about the hinge **1822** adjacent to the vertebrae and preferably to the lateral mass or to the lamina. Thus the lateral mass plate **1820** may be disposed at an angle relative to the natural or artificial facet joint spacer or inter-facet joint spacer **1810** for a representative spine configuration. It is to be understood that as this embodiment is hinged the final position of the lateral mass plate **1820** relative to the natural or artificial facet joint spacer or inter-facet joint spacer **1800** will depend on the actual spine configuration. It is to be understood that embodiments of the invention can be made without a hinge, as long as the connection between the natural or artificial facet joint spacer or inter-facet joint spacer and the lateral mass plate is flexible enough to allow the lateral mass plate to be bent relative to the natural or artificial facet joint spacer or inter-facet joint spacer in order to fit the anatomy of the patient. Once the lateral mass plate **1820** is positioned, or prior to the positioning of the lateral mass plate **1820**, a bore can be drilled in the bone to accommodate the bone screw **1824**. Alternatively the screw **1824** can be self-tapping. The screw is then placed through the bore **1830** and secured to the bone, preferably the lateral mass or the lamina, thereby holding the natural or artificial facet joint spacer or inter-facet joint spacer **1800** in place. In order to lock the bone screw **1824** in place and to lock the position of the natural or artificial facet joint spacer or inter-facet joint spacer **1800** and the lateral mass plate **1820** in place, the locking plate **1824** is positioned over the lateral mass plate **1820**. So positioned, the probe **1826** is positioned through the bore **1830** and against the head of the bone screw to keep the bone screw from moving. The keel **1828**, having a sharp chisel-shaped end, preferably can self-cut a groove in the bone so

that the keel **1828** is locked into the bone as the keel **1828** is aligned by, and received in, a groove **1831** of the lateral mass plate **1820**. Alternatively, a groove can be pre-cut in the bone to receive the keel **1828**. As this occurs the bore **1829** of the locking plate **1824** aligns with the threaded bore **1831** of the lateral mass plate **1820** and a machine screw can be inserted to lock the locking plate relative to the lateral mass plate.

5 This locking prevents the lateral mass plate **1820** and the natural or artificial facet joint spacer or inter-facet joint spacer **1810** from rotating and, as previously indicated, prevents the bone screw **1840** from backing out from the vertebra. Preferably the implant is between the C5 and C6 vertebrae level, or the C6 and C7 vertebrae level. It is noted that two implants preferably will be implanted at each level between vertebrae. That is, an implant **1800** will be placed in a right facet joint and also in a left facet joint when viewed from
10 a posterior view point. This procedure can be used to increase or distract the foraminal area or dimension of the spine in an extension or in neutral position (without having a deleterious effect on cervical lordosis) and reduce the pressure on the nerves and blood vessels. At the same time this procedure preserves mobility of the facet joint.

FIGs. 26A-27B show a further embodiment of the implant of the invention, with the embodiment
15 **2000** implanted in the cervical spine as depicted in **FIGs. 27A and 27B**. The implant **2000** comprises a first natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2010** and a second natural or artificial facet joint spacer or inter-facet joint spacer **2010**. Each natural or artificial facet joint spacer or inter-facet joint spacer can have a distal end **2012** that is tapered or wedge-shaped in a way that facilitates insertion into the cervical facet joints on both sides of two adjacent cervical vertebrae at the same
20 level. The natural or artificial facet joint spacer or inter-facet joint spacers further can be dome-shaped, or convex on a superior surface **2013**, to approximate the shape of the cervical facets of the cervical facet joints.

The first and second natural or artificial facet joint spacers or inter-facet joint spacers **2010** are bridged together by a collar **2015**. The collar **2015** passes between the spinous processes of the adjacent
25 cervical vertebrae. As can be seen in **FIG. 26B**, the implant can preferably be “V” shaped or “boomerang” shaped. The entire implant **2000** or the collar **2015** of the implant can be made of a flexible material such as titanium, so that it is possible to bend the collar **2015** so that it conforms preferably to the shape of the lateral mass or the lamina of the cervical vertebrae of the patient and thereby holds the implant in place with the natural or artificial facet joint spacer or inter-facet joint spacers **2010** inserted in the cervical facet
30 joints. Bores **2029** are preferably are provided through implant **2000** adjacent to the natural or artificial facet joint spacer or inter-facet joint spacer **2010** respectively. These bores **2029** can receive bone screws to position the implant **2000** against the lateral mass or the lamina as shown in **FIGs. 27A, 27B**. The description of the embodiment **2100**, in **FIGs. 28A, 28B** provide further details concerning the method of

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affixing the implant **2000** to the vertebrae. The implant **2100** also can be made of PEEK or other materials as described herein. Embodiment **2000** (the “boomerang” shape depicted in **FIG. 27B**) further can have a locking plate as, for example, the locking plate **1824** in **FIG. 22A**. The locking plate for embodiment **2000** (not shown) can have the same features as locking plate **1824**, that is: (1) a probe **1826** that interacts with the bone screws to prevent the bone screws from backing out of the bone, the likely consequence of which would be displacement of the implant **2000**; and (2) a keel **1828** with a chisel end to embed in the bone and thus to prevent rotational displacement of the implant. However, given the collar **2015** configuration of embodiment **2000**, a chisel may not serve the same purpose as with the embodiments set forth above, which lack a collar stabilized by two bone screws. Therefore, a locking plate on embodiment **2000** can be provided without a keel.

FIGs. 28A and 28B depict a further embodiment of the implant of the invention **2100**. In this embodiment **2100**, the collar **2115** can be made of a flexible material such as titanium, of a substantially inflexible material, or of other materials described herein. Substantial flexibility can also be derived from connecting a first natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2110** with the collar **2115** using a first hinge **2117**, and connecting a second natural or artificial facet joint spacer or inter-facet joint spacer **2110** with the collar **2115** using a second hinge **2117**. Using the first hinge **2117** and the second hinge **2117**, the collar **2115** can be pivoted downward to conform to a particular patient’s cervical spinal anatomy. In other words, the degree of pivoting will vary among different patients, and the first hinge **2117** and second hinge **2117** allow the implant **2100** to accommodate the variance.

In the hinged embodiment **2100**, and similar to the embodiment **2000**, the collar **2115** can have a first bore **2129** inferior to the first hinge **2117**, and a second bore **2129** inferior to the second hinge **2117**. A first bone screw penetrates the first bore **2130** and into the lateral mass or the lamina, and the second bone screw penetrates the second bore **2130** and into the lateral mass or the lamina, the first and second bone screws serving to anchor the implant. A bore, preferably in the lateral mass, can be drilled for the first bone screw and for the second bone screw. Alternatively, the bone screws can be self-tapping. A first locking plate similar to the plate **1924** (**FIG. 25A**) can be secured about the head of the first bone screw and a second locking plate can be secured about the head of the second bone screw to prevent displacement of the first and second bone screws **2140**. The first locking plate can block the first bone screw with a probe and the second locking plate can block to the second bone screw with a probe.

It should be noted that embodiments **2000** and **2100** also can be configured for accommodating treatment of cervical spinal stenosis and other cervical spine ailments where only a single cervical facet joint between adjacent vertebrae requires an implant, i.e., where treatment is limited to one lateral facet joint. In that case, the collar **2015**, **2115** extends medially without extending further to join a second

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natural or artificial facet joint spacer or inter-facet joint spacer **2010, 2110**. For the hinged embodiment **2100**, the implant comprises a single hinge **2117**, and the collar **2115** has only one bore **2129** to accept one bone screw to secure the implant **2100**.

FIGs. 29A-E, depict a sizing and distracting tool **2200** of the invention. Sizing tool **2200** has a handle **2203** and a distal head **2210** that is shaped as a natural or artificial facet joint spacer or inter-facet joint spacer (e.g., **1810**) of an implant of the invention. That is, the head **2210** preferably will have essentially the same features as the natural or artificial facet joint spacer or inter-facet joint spacer **1810**, but the dimensions of the head **2210** will vary from one tool **2200** to the next, in order to be able to use different versions of the sizing tool **2200** to determine the dimensions of the cervical facet joint that is to be treated and then to select an appropriately-sized implant. The head **2210** preferably can be used to distract the facet joint prior to the step of implanting the implant in the facet joint. In this regard, the head **2210** is rounded at the most distal point **2212**, and can be tapered to facilitate insertion into a cervical facet joint. The head **2210** also can have a slightly convex superior surface **2213**, the degree of convexity varying among different sizing tools **2200** in order to determine the desired degree of convexity of an implant to be implanted in the cervical facet joint. The head **2210** may have a uniform thickness along a proximal mid-section **2216**. Accordingly, the inferior surface **2215** preferably can be concave. Alternatively, the proximal mid-section **2212** may be convex on the superior surface **1813** without being uniform in thickness. Thus, the inferior surface **2215** can be flat or planar. The head also can be curved.

The head **2210** has a stop **2218** to prevent over-insertion of the head **2210** of the sizing tool **2200** into the facet joint. The stop **2218** can be a ridge that separates the head **2210** from the handle **2203**. Alternatively, the stop **2218** can be any structure that prevents insertion beyond the stop **2218**, including pegs, teeth, and the like.

Different sizing tools **2200** covering a range of dimensions of the head **2210** can be inserted successively into a cervical facet joint to select the appropriate size of an implant to position in the cervical spine, with the appropriate convexity and concavity of natural or artificial facet joint spacer or inter-facet joint spacer. Each preferably larger head also can be used to distract the facet joint.

FIG. 31A depicts a posterior view of a further embodiment **2300** of the implant of the invention. Embodiment **2300**, as well as all of the embodiments herein, can benefit from some or all of the advantages described herein with regard to the other embodiments described herein. Further, **FIG. 31A**, embodiment **2300** has a natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2310** that can have a tapered or thinned distal end **2312** so that the distal end **2312** facilitates insertion of the natural or artificial facet joint spacer or inter-facet joint spacer **2310** into a cervical facet joint. The distal end **2312** can be rounded, as seen in the plan view of **FIG. 31A**, in order to conform to the roundness of the facet

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joint. The natural or artificial facet joint spacer or inter-facet joint spacer **2310** further can be curved so that a superior surface **2313** of the natural or artificial facet joint spacer or inter-facet joint spacer **2310** is convex, and an inferior surface **2315** is concave, to approximate the natural shape of the cervical facet joint that is to receive the implant **2300**. The curve can have a uniform thickness, or it can have a varied thickness. Further, the lateral edges of the natural or artificial facet joint spacer or inter-facet joint spacer **2310** are curved or rounded, for distribution of load-bearing stress. As with other embodiments described herein, the natural or artificial facet joint spacer or inter-facet joint spacer **2310** also can be made of a flexible, biocompatible material, such as PEEK, to maintain joint mobility and flexibility.

The natural or artificial facet joint spacer or inter-facet joint spacer **2310** is connected flexibly with a lateral mass plate **2320**, the flexible connection preferably being a hinge **2322**. As seen in the plan view of **FIG. 31A**, the implant **2300** is substantially hour-glass shaped. This shape, as well as the shape of **FIG. 32**, will be discussed further below. The hinge **2322** is narrower than the natural or artificial facet joint spacer or inter-facet joint spacer **2310**, with the hinge **2322** sitting at substantially the isthmus **2317** between natural or artificial facet joint spacer or inter-facet joint spacer **2310** and the lateral mass plate **2320**. The curved edges, or fillets, about the hinge **2322** serve to distribute more evenly the load-bearing stress on the implant **2300**, and thus prevent concentrating the stress about the edges.

The hinge **2322** allows the implant **2300** to bend at the hinge **2322**, bringing a lateral mass plate **2320** adjacent to the lateral mass and/or lamina of the patient's spine, and to conform to a particular patient's anatomy. The lateral mass plate **2320** is made of a biocompatible flexible material, preferably titanium or any other biocompatible flexible material as described herein, for example PEEK, that will support the use of bone screws and other hardware, as described below. The lateral mass plate **2320** bends downward at the hinge **2322** over a wide range of angles relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2310**, and preferably at an angle of more than 90 degrees, and this flexibility facilitates positioning and insertion of the natural or artificial facet joint spacer or inter-facet joint spacer. This flexibility of the lateral mass plate **2320** relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2310** further facilitates positioning of the lateral mass plate relative to the lateral mass and/or the lamina of the patient's spine. Once the lateral mass plate **2320** is positioned adjacent to the bone, preferably the lateral mass of a cervical vertebra, a first bone screw, such as bone screw **1840**, can be inserted through a first bore **2330** through the lateral mass plate **2320** and embedded into the bone of the lateral mass of the cervical vertebra.

The lateral mass plate **2320** further comprises a second bore **2329** which is preferably positioned medially, relative to the first bore **2330**. Thus, viewing the implant from a posterior perspective as in **FIG. 31A**, the second bore **2329** in the lateral mass plate **2320** can be positioned either to the left or to the right

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of the first bore **2330**. The position of the second bore **2329** will depend upon whether the implant **2300** is intended to be inserted into a cervical facet joint on the left or right side of a patient. Specifically, an implant **2300** to be inserted into a right-side cervical facet joint (i.e., the patient's right side) will have a second bore **2329** positioned to the left of the first bore **2330** as in **FIG. 31A**, when implant **2300** is viewed from a posterior perspective, while an implant **2300** to be inserted into a left-side cervical facet joint will have a second bore **2329** positioned to the right of the first bore **2330**, when implant **2300** is viewed from a posterior perspective.

The second bore **2329** through the lateral mass plate **2320** is adapted to accept a second screw **2390** (**FIG. 31B**), which preferably is a locking screw with a chisel point **2391**. The locking screw **2390** is received by the second bore **2329** and the chisel point **2391** self-cuts a bore into the bone. The locking screw **2390** preferably is inserted through the second bore **2329** and embedded in the bone, after the bone screw is embedded in the bone through the first bore **2330**. The position of the second bore **2329**, i.e., medial to the first bore **2330**, positions the locking screw **2390** so that it embeds in stronger bone tissue than if the second bore **2329** were located more laterally. The locking screw, in combination with the bone screw, prevents rotational and/or backward displacement of the implant **2300**. As the locking screw **2390** is received by the second bore **2329**, the head **2392** of the locking screw **2390** aligns with the head of the first bone screw in the first bore **2330**, blocking the head of the first bone screw to prevent the first bone screw from backing out of the bone of the vertebra and the first bore **2330**.

FIG. 32 depicts a further embodiment **2400** of the implant of the invention, from a posterior view. Embodiment **2400** is adapted to be implanted in a manner that preserves the anatomy of the cervical facet joint, in particular, the soft tissues around the cervical facet joint, including the joint capsule.

Implant **2400**, like implant **2300** and other implants disclosed above, has a natural or artificial facet joint spacer (or inert) or inter-facet joint spacer (or insert) **2410**, flexibly connected, preferably by a hinge **2422**, to a lateral mass plate **2420**. As can be seen in **FIG 32**, the implant **2400** including the natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2410** and the hinge **2422** is substantially "P" shaped. As explained below, its "P" shape assists in the insertion of the implant **2400** into the facet joint with most of the facet capsule and facet capsule ligament and other soft tissue associated with the facet joint still left intact. The natural or artificial facet joint spacer or inter-facet joint spacer, as above for implant **2300** and the other implants disclosed above, can have a superior surface **2413** of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** that is convex, and an inferior surface **2415** that is concave, or any appropriate shaping to approximate the natural shape of the cervical facet joint that is to receive the implant **2400**. The thickness of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** can be uniform, or varied. The natural or artificial facet joint spacer or inter-facet joint

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spacer **2410** also can be made of a flexible, biocompatible material, such as PEEK, to maintain joint mobility and flexibility. The hinge **2422** can have smooth, rounded edges, for distribution of load stress, as disclosed above. Other features and advantages of the other embodiments can be, if desired, incorporated into the design of the embodiment of **FIG. 32**. For example, the natural or artificial facet joint spacer or inter-facet joint spacer **2410** further can have a tapered or thinned edge **2412** so that the edge **2412** facilitates insertion of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** into a cervical facet joint. The edge **2412** can be curved. In this embodiment **2400**, however, the thinned edge **2412** of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** preferably is not at the distal end of the natural or artificial facet joint spacer or inter-facet joint spacer **2400** as is the thinned edge **2312** of the natural or artificial facet joint spacer or inter-facet joint spacer **2300**; rather, the thinned edge **2412** preferably is positioned laterally, toward the hinge **2422** of the implant **2400**. The thinned edge **2412** coincides substantially with a lateral curvature **2440** of the natural or artificial facet joint spacer or inter-facet joint spacer **2410**, which is pronounced relative to the curvature on the medial side of the implant **2400**, i.e., a "P" shape. In other words, the curved part of the head of the "P" **2440** corresponds to the thinned edge **2412**, and serves as the leading edge of the implant **2400** to begin insertion of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** into a cervical facet joint, preferably through an incision in the soft tissue of the facet joint. The "P" shape narrows at isthmus **2417** where the natural or artificial facet joint spacer or inter-facet joint spacer **2410** that is joined by the hinge **2422** with the lateral mass plate **2420**. The smooth or rounded edges or fillets serve to distribute stresses on the implant **2400**. The above described "P" shape of implant **2400** allows the implant **2400** to be pivoted into place into a facet joint as described below. The thinned edge **2412** and leading lateral curvature **2440** of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** are adapted to facilitate urging implant **2400** into the cervical facet joint, through the incision in the joint capsule. The implant **2400** then is pivoted into position so that the lateral mass plate **2420** can be bent downward, relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2410**, to align with and lie adjacent to the lateral mass and/or the lamina. The lateral mass plate **2420** is then fastened to the bone.

The lateral mass plate **2420** of implant **2400**, like the lateral mass plate for implant **2300**, is flexibly connected, preferably by the smooth-edged hinge **2422**, to the natural or artificial facet joint spacer or inter-facet joint spacer **2410** at the narrow lower part of the natural or artificial facet joint spacer or inter-facet joint spacer. The lateral mass plate **2420** is made of a biocompatible flexible material, preferably titanium or any other biocompatible flexible material such as PEEK that will support the use of bone screws and other hardware, as described below.

The lateral mass plate **2420** bends downward at a wide range of angles relative to the natural or

artificial facet joint spacer or inter-facet joint spacer **2410**, and preferably at an angle of more than 90 degrees. The flexibility of the lateral mass plate **2420** relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2410** further facilitates positioning of the lateral mass plate **2420** relative to the lateral mass and/or the lamina of the patient's spine.

5 Like embodiment **2300**, described above, the lateral mass plate **2420** has first bore **2430**, which is adapted to receive a bone screw **2440**, to help anchor implant **2400** in position. The lateral mass plate **2420** further includes a second bore **2429** adapted to be positioned medially, relative to the first bore **2430**, as disclosed above for implant **2300**. The position of the second bore **2429**, when viewing implant **2400** from a posterior perspective (**FIG. 32**), will depend upon whether implant **2400** is intended to be implanted into a left-side or right-side cervical facet joint of a patient. Thus, implant **2400** with the second bore **2429** positioned to the left of the first bore **2430** is intended to be implanted in a right-side cervical facet joint of a patient, as depicted in **FIG. 32**, while an implant **2400** with a second bore **2429** positioned to the right of the first bore **2430** is intended to be implanted in a left-side cervical facet joint of a patient.

15 The second bore **2429** through the lateral mass plate **2420** is adapted to receive a second screw **2490** with head **2492**, which preferably is a locking screw with a chisel point, such as screw **2390**. The function and purpose of the bone screw disposed through bore **2430** and the locking screw disposed through bore **2429** are as described above with respect to the implant **2300**.

20 The present invention further includes a method of implanting the implant **2400** (**FIGS. 33A, 33B**). To insert the natural or artificial facet joint spacer or inter-facet joint spacer **2410**, a facet joint is accessed and an incision or a pair of incisions is made in the capsular ligament, the joint capsule, and the synovial membrane so that the thinned edge **2412** of the implant **2400** can be urged into the cervical facet joint through these tissues. The capsular ligament and the joint capsule and other soft tissues around the cervical facet joint are allowed to remain substantially intact, except for the small incision, and will be sutured and allowed to heal around the implant **2400**. If desired, the cervical facet joint can be distracted prior to urging the curved section **2440** with the thinned edge **2412** of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** into the cervical facet joint. Once the curved section **2440** of the natural or artificial facet joint spacer or inter-facet joint spacer **2410** with the thinned edge **2412** is urged into the cervical facet joint, implant **2400** is pivoted, preferably about 90 degrees, so that the second bore **2429** is placed medially relative to the first bore **2430**. This allows the natural or artificial facet joint spacer or inter-facet joint spacer **2410** to be positioned in the facet joint. It is noted that the overall size, including the isthmus **2417**, of the natural or artificial fact joint **2410**, as that of **2310**, can be somewhat smaller than in prior embodiments to allow the natural or artificial facet joint spacer or inter-facet joint spacer to be positioned within the edges of the facet joint with the joint capsule substantially intact. The lateral mass

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plate **2420** then can be bent downward about the hinge **2422** into position adjacent the lateral mass or lamina of the spine of the patient, which position will depend upon the anatomy of an individual patient's cervical spine.

Once the lateral mass plate **2420** is positioned adjacent to the bone, preferably the lateral mass of a cervical vertebra, a first bone screw can be inserted through the first bore **2430** through the lateral mass plate **2420** and become embedded into the bone of the lateral mass of the cervical vertebra to anchor the implant **2400**. After the bone screw is embedded, a locking screw is inserted through the second bore **2429** of the lateral mass plate **2420**, the second bore **2429** medial to the first bore **2430**. The locking screw has a chisel end that allows the locking screw to dig into the bone without use of a tool to pre-cut a bore. Alternatively, a bore can be pre-cut and a locking screw without a chisel end can be used. As the locking screw is embedded in the bone, the locking head of the locking screw is brought into proximity with the head of the bone screw to block its backward movement so that the implant **2400** remains anchored with the bone screw, i.e., so that the bone screw cannot back out of the bone. The embedded locking screw also serves to prevent rotational displacement of implant **2400**, while blocking backward displacement of the first bone screw.

Referring to **FIGs. 34A** through **36B**, a still further embodiment of an implant **2500** in accordance with the present invention can include a natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2510** connected with a lateral mass plate (also referred to herein as an anchoring plate) **2520** by a spheroidal joint arrangement **2538** or otherwise shaped multiple direction articulation joint arrangement. The natural or artificial facet joint spacer or inter-facet joint spacer **2510** has a load bearing structure sized and shaped to distribute, as desired, a load applied by opposing surfaces of superior and inferior facets to one another. As shown, the load bearing structure has a saucer shape, but as described in further detail below (and as described in previous embodiments above), in other embodiments the load bearing structure can have some other shape so long as a desired load distribution and separation between superior and inferior facets is achieved. The natural or artificial facet joint spacer or inter-facet joint spacer **2510** includes a handle-like structure connected with the load bearing surface, the handle-like structure necking at an isthmus **2517** and terminating at a pivot end **2526**. In an embodiment, the pivot end **2526** is substantially spherical, ovoidal, or similarly rounded in shape. As further described below, the natural or artificial facet joint spacer or inter-facet joint spacer **2510** can comprise a flexible material, for example a biocompatible polymer such as PEEK, or a more rigid material, for example a biocompatible metal such as titanium. As shown, the lateral mass plate **2520** has a generally square shape with rounded corners; however, in other embodiments the lateral mass plate **2520** can have any number of shapes so long as the lateral mass plate **2520** provides sufficient support for anchoring the implant **2500** in position and so long as the lateral mass plate **2520** allows a desired range of motion for the natural or artificial facet joint spacer

or inter-facet joint spacer **2510**. The lateral mass plate **2520** includes a cavity **2527** within which the pivot end **2526** is held. The spheroidal joint arrangement **2538** comprises the pivot end **2526** and the cavity **2527** and as described below allows the natural or artificial facet joint spacer or inter-facet joint spacer **2510** to tilt and swivel relative to the lateral mass plate **2520**.

5 **FIG. 34A** is a posterior view showing a posterior face **2532** of the lateral mass plate **2520**, while **FIG. 34B** is an anterior view showing an anterior face **2534** of the lateral mass plate **2520**. The lateral mass plate **2520** includes an anterior notch **2524** (see **FIG. 35**) or other indentation formed along the edge of the anterior face **2534** and a posterior notch **2522** or other indentation formed along the posterior face **2532**. The posterior and anterior notches **2522,2524** are generally aligned with one another along the edge
10 of the lateral mass plate **2520** and are connected with the cavity **2527**. The notches **2522,2524** confine movement of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** in the anterior and posterior directions relative to the lateral mass plate **2520**, allowing the natural or artificial facet joint spacer or inter-facet joint spacer **2510** to tilt at varying degrees of angle in an anterior and posterior direction. Referring to **FIG. 35**, the anterior notch **2524** can have a narrower width than the posterior
15 notch **2522** which is sized to provide the pivot end **2526** of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** with access to the cavity **2527** so that the pivot end **2526** can be inserted into the cavity **2527**. Once the pivot end **2526** is positioned within the cavity **2527** a plug **2528** can be mated with the lateral mass plate **2520** to lock the pivot end **2526** in place within the cavity **2527** and to further limit freedom of movement of the natural or artificial facet joint spacer or inter-facet joint spacer **2510**,
20 particularly limiting tilting of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** in a posterior direction. The plug **2528** can be press fit to the posterior notch **2522** and further welded or otherwise fixedly fastened with the lateral mass plate **2520**. A physician can select an appropriate and/or desired natural or artificial facet joint spacer or inter-facet joint spacer **2510**, lateral mass plate **2520**, and plug **2528** according to the motion segment targeted for implantation and/or the particular anatomy of the
25 patient. Once an appropriate combination of components is identified, the natural or artificial facet joint spacer or inter-facet joint spacer **2510** and the lateral mass plate **2520** can be mated, and the natural or artificial facet joint spacer or inter-facet joint spacer **2510** can be locked in place by the plug **2528**.

As can further be seen in **FIGs. 34A** through **35** the lateral mass plate **2520** has a first bore **2530** therethrough. The first bore **2530** can accept a bone screw **2540** (also referred to herein as a lateral mass
30 screw) to secure the lateral mass plate **2520** preferably to the lateral mass, lamina, or alternatively to another part of the spine, and thus to anchor the implant **2500**. The lateral mass screw **2540** preferably has a head **2542** that can accept a tool chosen for the surgical procedure whether a wrench, screwdriver, or other tool. The lateral mass plate **2520** further has a second bore **2529** which is preferably positioned

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medially, relative to the first bore **2530**. Referring to **FIG. 34A**, the second bore **2529** in the lateral mass plate **2520** can be positioned either to the left or to the right of the first bore **2530**. The position of the second bore **2529** will depend upon whether the implant **2500** is intended to be inserted into a cervical facet joint on the left or right side of a patient. Specifically, an implant **2500** to be inserted into a right-side cervical facet joint (i.e., the patient's rights side) will have a second bore **2529** positioned to the left of the first bore **2530** as in **FIG. 34A**, when implant **2500** is viewed from a posterior perspective, while an implant **2500** to be inserted into a left-side cervical facet joint will have a second bore **2529** positioned to the right of the first bore **2530**, when implant **2500** is viewed from a posterior perspective.

The second bore **2529** through the lateral mass plate **2520** is adapted to accept a second screw **2590** which preferably is a locking screw having a chisel point **2591**. The locking screw **2590** is received by the second bore **2529** and the chisel point **2591** self-cuts a bore into the bone. The locking screw **2590** is preferably inserted through the second bore **2529** and embedded in the bone after the bone screw **2540** is embedded in the bone through the first bore **2530**. The medial position of the second bore **2529** relative to the first bore **2530** positions the locking screw **2590** so that it embeds in stronger bone tissue than if the second bore **2529** were located more laterally. The locking screw **2590**, in combination with the bone screw **2540**, prevents rotational and/or backward displacement of the lateral mass plate **2520**. As the locking screw **2590** is received by the second bore **2529**, the head **2592** of the locking screw **2590** aligns with the head **2542** of the first bone screw **2540** in the first bore **2530**, blocking the head **2542** of the first bone screw **2540** to prevent the first bone screw **2540** from backing out of the bone of the vertebra and the first bore **2530**. The posterior face **2532** can include a recessed portion **2539**, and/or the second bore **2529** can be countersunk, so that the locking screw **2590** does not protrude farther from the posterior face **2532** than desired.

In a preferred embodiment (as shown in **FIGs. 34A-37**), the spheroidal joint arrangement **2538** includes a spherical pivot end **2526** and a cavity **2527** having a shape approximately conforming to the spherical pivot end **2526** so that the spheroidal joint arrangement **2538** is a ball-in-socket arrangement. The ball-in-socket arrangement **2538** allows the natural or artificial facet joint spacer or inter-facet joint spacer **2510** to move freely relative to the lateral mass plate **2520** where the natural or artificial facet joint spacer or inter-facet joint spacer **2510** is unobstructed by the lateral mass plate **2520**. For example, as shown in **FIG. 36A** the natural or artificial facet joint spacer or inter-facet joint spacer **2510** can tilt in an anterior direction (to position 1, for example) and can tilt in a posterior direction (to position 2, for example). As the natural or artificial facet joint spacer or inter-facet joint spacer **2510** tilts in an anterior direction, the isthmus **2517** moves within the anterior notch **2524** so that the natural or artificial facet joint spacer or inter-facet joint spacer **2510** can continue tilting without obstruction. Conversely, as the natural

or artificial facet joint spacer or inter-facet joint spacer **2510** tilts in a posterior direction (to position 2, for example), the isthmus **2517** contacts the plug **2528**, limiting the amount of tilt of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** in a posterior direction.

Referring to **FIG. 36B**, the ball-and-socket arrangement allows the natural or artificial facet joint spacer or inter-facet joint spacer **2510** to swivel (to position 3, for example) relative to the lateral mass plate **2520**, potentially providing a more conformal arrangement of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** with the surfaces of the superior and inferior facets. Further, the ability of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** to swivel can increase options for lateral mass plate **2520** anchor positions. A physician can anchor the lateral mass plate **2520** in a more conformal or advantageous orientation and/or position along the lateral mass, for example, by altering the arrangement of the lateral mass plate **2520** relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2510**. The amount of swiveling accommodated (and the degree of freedom of movement accommodated in general) depends on the geometries of the components. For example, where the isthmus **2517** is sufficiently narrow and long in length, a greater degree of swiveling in combination with tilt can be achieved, or for example where the plug **2528** extends over a portion of the natural or artificial facet joint spacer or inter-facet joint spacer **2510**, as shown in **FIGs. 36A** and **36B**, the amount of tilt possible in the posterior direction can be limited. One of ordinary skill in the art will appreciate that the freedom of movement of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** relative to the lateral mass plate **2520** is limited substantially or wholly by the geometries of the components, and therefore can be substantially altered to achieve a desired range of movement. The ball-and-socket arrangement need not include a ball that extends from the natural or artificial facet joint spacer or inter-facet joint spacer and a socket that is formed in the lateral mass plate. For example, the ball of such a joint can extend from a locking or anchoring plate and the socket can be included in the natural or artificial facet joint spacer or inter-facet joint spacer. Further, while the preferred embodiment has been described as a ball-and-socket arrangement, other arrangements can be employed with varied results. It should not be inferred that embodiments in accordance with the present invention need include a spheroidal shaped end mated with a rounded cavity. The scope of the present invention is not intended to be limited to ball-and-socket arrangements, but rather is intended to encompass all such arrangements that provide a plurality of degrees of freedom of movement and substitutability of components.

Referring again to **FIGs. 36A** and **36B**, the load bearing structure of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** includes a superior surface **2513** having a generally convex shape and an inferior surface **2514** having a slightly concave shape. The shape of the load bearing structure is intended to approximate a shape of opposing surfaces of the superior and inferior facets. The shape of the superior and inferior surfaces **2513,2514** can vary between motion segments and between

patients. For example, as shown in **FIG. 37**, where the cervical vertebra includes an inferior facet having a substantially convex natural surface, a physician may select a natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2610** including a load bearing structure with an inferior surface **2614** having a more concave shape combined with a lateral mass plate **2620** having a bone screw **2640** more appropriately sized for the particular lateral mass to which it will be fixed. (As shown the bone screw **2640** has a shorter length and wider diameter.) A physician can be provided with a natural or artificial facet joint spacer or inter-facet joint spacers having a multiplicity of load bearing structure shapes. As mentioned above, the ability to match different natural or artificial facet joint spacer or inter-facet joint spacers with different lateral mass plates can improve a physician's ability to provide appropriate treatment for a patient, and can further provide the physician flexibility to reconfigure an implant once a surgical site has been exposed and the physician makes a determination that a different combination of components is appropriate.

In yet another embodiment, the spheroidal joint arrangement **2538** of **FIGs. 34A-37** can be applied to collar structures, for example as shown in **FIGs. 26A-27B** so that the natural or artificial facet joint spacer or inter-facet joint spacers at each end of the collar structure include an increased range of motion to improve surface matching between the natural or artificial facet joint spacer or inter-facet joint spacers and the surfaces of the superior and inferior facets (i.e., increasing the amount of facet surface area contacting the natural or artificial facet joint spacer or inter-facet joint spacers).

FIG. 38 is a flow chart of an embodiment of a method in accordance with the present invention for implanting an implant as described in **FIGs. 34A** through **37**. An incision must first be made to expose the surgical site and access the targeted facet joint (Step **2500**). Once the facet joint is made accessible, the facet joint can be sized and distracted (Step **2502**). A sizing tool **2200** (for example, see **FIGs. 29A-C**) can be inserted to select the appropriate size of an implant **2500** of the invention for positioning in the cervical facet joint. This step may be repeated as necessary with, if desired, different sizes of the tool **2200** until the appropriate size is determined. This sizing step also distracts the facet joint and surrounding tissue in order to facilitate insertion of the implant **2500**. Once the appropriate size is determine, the physician can select an appropriate natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2510** with the lateral mass plate **2520** (Step **2504**). The natural or artificial facet joint spacer or inter-facet joint spacer **2510** can then be urged between the facets into the facet joint (Step **2510**). The facet itself is somewhat shaped like a ball and socket joint. Accordingly, in order to accommodate this shape, the natural or artificial joint **2510** can have a rounded leading edge shaped like a wedge or tissue expander to cause distraction of the facet joint as the natural or artificial facet joint spacer or inter-facet joint spacer is urged into the facet joint of the spine. The natural or artificial facet joint spacer or inter-facet joint spacer **2510** also includes the convex superior surface **2513** in order to more fully accommodate the shape of the facet

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joint of the spine. However, as set forth above and as depicted in **FIG. 37**, it is possible in the alternative to have a curve-shaped natural or artificial facet joint spacer or inter-facet joint spacer **2610** with a convex superior surface **2613** and a concave inferior surface **2614**, the distal end of the natural or artificial facet joint spacer or inter-facet joint spacer **2610** tapering to facilitate insertion, while the remainder of the natural or artificial facet joint spacer or inter-facet joint spacer **2610** has a uniform thickness.

Once the natural or artificial joint **2510** is positioned, the lateral mass plate **2520** is tilted and/or swiveled so that the lateral mass plate **2520** is adjacent to the vertebrae and preferably to the lateral mass or to the lamina (Step **2512**). Thus the lateral mass plate **2520** may be disposed at an angle relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2510** for a representative spine configuration. It is to be understood that the final position of the lateral mass plate **2520** relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2510** will depend on the actual spine configuration. Once the lateral mass plate **2520** is positioned, or prior to the positioning of the lateral mass plate **2520**, a bore can be drilled in the bone to accommodate the bone screw **2540**. Alternatively the screw **2540** can be self-tapping. The screw **2540** is then placed through the first bore **2530** and secured to the bone, preferably the lateral mass or the lamina, thereby holding the natural or artificial facet joint spacer or inter-facet joint spacer **2510** in place (Step **2514**). In order to lock the bone screw **2540** in place and to lock the position of the natural or artificial facet joint spacer or inter-facet joint spacer **2510** and the lateral mass plate **2520** in place, a self-tapping locking screw **2590** is positioned within a second bore **2529** of the lateral mass plate **2520** and secured to the bone, thereby resisting undesirable movement of the lateral mass plate **2520** (Step **2516**). A head **2592** of the locking screw **2590** can further block movement of the bone screw **2540** by trapping the bone screw head **2542** between the locking screw head **2592** and the first bore **2530**. The locking screw **2590** therefore prevents the lateral mass plate **2520** and the natural or artificial facet joint spacer or inter-facet joint spacer **2510** from rotating and, as previously indicated, prevents the bone screw **2540** from backing out from the vertebra. Preferably the implant is between the C5 and C6 vertebrae level, or the C6 and C7 vertebrae level. It is noted that two implants preferably will be implanted at each level between vertebrae. That is, an implant will be placed in a right facet joint and also in a left facet joint when viewed from a posterior view point. This procedure can be used to increase or distract the foraminal area or dimension of the spine in an extension or in neutral position (without having a deleterious effect on cervical lordosis) and reduce the pressure on the nerves and blood vessels. At the same time this procedure preserves mobility of the facet joint.

FIG. 39A depicts a posterior view of another embodiment **2600** of the implant of the invention. Embodiment **2600**, as well as all of the embodiments herein, can benefit from some or all of the features and advantages with regard to the other embodiments described herein. As shown, embodiment **2600** has a

natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2610** that can have a tapered or thinned distal end **2612**. The natural or artificial facet joint spacer or inter-facet joint spacer **2610** further can be curved so that a superior surface **2613** of the natural or artificial facet joint spacer or inter-facet joint spacer **2610** is convex, and an inferior surface **2615** is concave, to approximate the natural shape of the cervical facet joint that is to receive the implant **2600**. In one embodiment, the inferior surface **2615** is substantially flat whereby the superior surface **2613** is convex (**FIG. 39B**). As shown in **FIG. 39B**, the convex superior surface **2613** tapers downward at an increased angle toward the inferior surface **2615** at the distal end **2612**. This contour of the superior surface **2613** aids in smooth insertion of the natural or artificial facet joint spacer or inter-facet joint spacer **2610** into the facet joint. As with other embodiments described above, the natural or artificial facet joint spacer or inter-facet joint spacer **2610** also can be made of a flexible, biocompatible material, such as PEEK, to maintain joint mobility and flexibility.

The natural or artificial facet joint spacer or inter-facet joint spacer **2610** is connected flexibly with the lateral mass plate **2620**, preferably with a hinge **2622**. The hinge **2622** allows the natural or artificial facet joint spacer or inter-facet joint spacer **2610** and the lateral mass plate **2620** of the implant **2600** to bend with respect to one another between an extended position and a bent or folded position as discussed above. Once the lateral mass plate **2620** is positioned adjacent to the bone, preferably the lateral mass of a cervical vertebra, a first bone screw, such as bone screw **1840**, can be inserted through a first bore **2630** through the lateral mass plate **2620** and embedded into the bone of the lateral mass of the cervical vertebra.

In addition, once the lateral mass plate **2620** is secured with the first bone screw, a second bone screw can be inserted through a second bore **2629** in the lateral mass plate **2620**, whereby the second bone screw would be embedded into the bone of the lateral mass of the cervical vertebra. Details of the first and second bores are discussed above.

The lateral mass plate **2620** is made of a biocompatible flexible material, preferably titanium or any other biocompatible flexible material as described herein, for example PEEK, that will support the use of bone screws and other hardware, as described below. The lateral mass plate **2620** bends downward about the hinge **2622** over a wide range of angles relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2610**. In another embodiment, any other type of interface between the natural or artificial facet joint spacer or inter-facet joint spacer **2610** and the lateral mass plate **2610** is contemplated (e.g. ball and socket joint). This flexibility facilitates positioning and insertion of the natural or artificial facet joint spacer or inter-facet joint spacer **2610**.

FIG. 39B depicts a side view of the natural or artificial facet joint spacer or inter-facet joint spacer and lateral mass plate in accordance with one embodiment. As shown in **FIG. 39B**, the natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2610** includes an hyper-extension tab **2622**

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in one embodiment. The hyper-extension tab **2622** prevents the natural or artificial facet joint spacer or inter-facet joint spacer **2610** as well as the lateral mass plate **2620** from moving in a direction beyond the extended position which is shown in **FIGS. 39A and 39B**. The lateral mass plate **2620** preferably includes a recess **2611** at the interface between the lateral mass plate **2620** and the natural or artificial facet joint spacer or inter-facet joint spacer **2610** which seats the tab **2622** in the extended position which is shown in **FIG. 39A**. When the natural or artificial facet joint spacer or inter-facet joint spacer **2610** is bent at an angle, the tab **2622** is not in contact with the recess **2611**. However, the tab **2622** comes into contact with the recess **2611** when in the extended position, as shown in **FIG. 39A**. In addition, the tab **2622**, when seated in the recess **2611**, prevents the natural or artificial facet joint spacer or inter-facet joint spacer **2610** and lateral mass plate **2620** from moving beyond the extended position. This features aids in placing the implant into the facet joint as the implant is prevented from bending back beyond the extended position shown in **FIG. 39B**. This arrangement, however, allows the lateral mass plate **2620** to bend down to meet the spine when the natural or artificial facet joint **2610** is implanted in the facet joint.

As shown in **FIG. 39A**, the lateral mass plate **2620** preferably includes a third bore **2602** located near a rear edge, whereby the third bore **2602** preferably receives an engaging rod **2716** (**FIG. 40B**) of an implantation tool **2600** described below. The third bore **2602** preferably extends through the superior and inferior surfaces of the lateral mass plate, although not necessarily. Although the third bore **2602** is circular in shape, any other shape is contemplated which engages a correspondingly shaped engaging rod **2716** (**FIG. 40B**). The rear edge **2604** of the lateral mass plate **2620** can be engaged by the engagement head **2706** (**FIG. 40B**) of the implantation tool **2700** as described below.

In addition, the lateral mass plate **2620** preferably includes one or more winged protrusions, such as tabs, winglets or ears, **2608** which protrude from the side edges of the lateral mass plate **2620**. **FIG. 39A** illustrates the implant **2600** having two winged protrusions **2608**. The protrusions **2608** serve as guides to successfully couple the implant **2600** to the implantation tool **2700**. In addition, the protrusions act as an engaging mechanism which secures the implant **2600** to the tool **2700**. It should be noted that the winged protrusions **2608** are preferred and the implant **2600** can be configured in any other appropriate design to ensure that the implant **2600** is able to be effectively guided and secured to the implantation tool **2700**.

FIG. 40A depicts an implantation tool in accordance with one embodiment of the present invention. As shown in **FIG. 40A**, the tool **2700** preferably includes a handle **2702** having a proximal end and a distal end. The tool **2700** includes an actuating switch **2708** as well as a shaft **2704** extending from the distal end of the handle **2702**. As shown in **FIG. 40A**, the shaft **2704** preferably extends axially with the handle **2702**, although the shaft **2704** may be at an angle with respect to the handle **2702**. Extending

from the shaft 2704 is an engagement head 2706, whereby the engagement head is preferably oriented at an angle with respect to the shaft 2704 and/or the handle 2702. The angle of the head 2706 relative to the shaft 2704 aids the surgeon in the process of implanting the implant 2600 in the spine. This angle allows the surgeon to slip the natural or artificial facet joint spacer or inter-facet joint spacer 2620 into the facet joint with the tool 2700 preferably about a right angle to the spine. Preferably the head is at an angle between 45 and 90 degrees relative to the handle 2704. However, other angles are contemplated.

Referring to FIG. 40B, the engagement head 2706 preferably has a forked configuration and includes a pair of side walls 2710, an engagement seat 2712 as well as a receiving space 2718 which is defined as the area between the side walls 2710 and the seat 2712. The engagement head 2706 preferably includes a retractable engaging rod 2716 which extends partially into the receiving space 2618. The side walls 2610 each have an inner side which includes a slot 2712 whereby the slots 2712 face the receiving space 2718. The slots 2712 are dimensioned to slidably receive the wing protrusions 2608 of the lateral mass plate 2620 as well as secure the lateral mass plate 2620 to the engagement head 2706. The engagement seat 2712 receives the rear edge 2604 of the lateral mass plate 2620.

In one embodiment, the engagement head 2706 preferably includes the engaging rod 2716, as shown in FIG. 40B. The engaging rod 2716 is dimensioned to fit within the third bore 2602 in the lateral mass plate 2620. The engaging rod 2716 is coupled the switch 2708 on the handle 2702, whereby actuation of the switch 2708 causes the engaging rod 2716 to retract. Upon being retracted, the engaging rod 2716 disengages the third bore 2602 and allows the implant 2600 to be disengaged from the engagement head 2706. It is preferred that the tool 2700 includes a spring or other urging means to urge the engaging rod 2716 to the extended position, as shown in FIG. 40B. In another embodiment, the engaging rod 2716 is freely moveable between the extended and retracted positions without a biasing force applied thereto.

It should be noted that the engaging rod 2716 is shown as being a circular cylinder in FIGS. 40A and 40B. However, it is contemplated that the engaging rod 2716 can have any other shape which conforms to the shape of the third bore 2602 in the lateral mass plate 2620. In another embodiment, the engagement head 2706 does not include an engaging rod 2716 but some other mechanism to secure the implant 2600 to the tool 2700. In yet another embodiment, the slots 2712 in the side walls 2710 can be used to retain the implant 2600 in the head 2706 without the use of an engaging mechanism.

In preferred operation, to engage the implant 2600 with the tool 2700, the implant 2700 is oriented to be right side up such that the rear surface 2604 of the implant 2600 will conform and mate with the engagement seat 2714. The implant 2600 is aligned with the forked portion of the engagement head 2706, whereby the winged protrusions 2608 of the implant 2600 are inserted into the slot openings 2712. Upon

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registering the winged protrusions **2608** into the corresponding slots **2712**, the lateral mass plate **2620** is guided into engagement by the slots **2712** until the rear edge **2604** mates with the engagement seat **2714**. Preferably the engaging rod **2716** is then inserted into the third bore **2602**, thereby securing the lateral mass plate **2620** to the engagement head **2706**. In one embodiment, the user manually actuates the switch **2708** to retract the engaging rod **2716** to allow the lateral mass plate **2620** to be inserted completely in the receiving space. The switch **2708** is then manually released when the bore **2602** and engaging rod **2716** are aligned such that the engaging rod **2716** then extends and engages the third bore **2602**. In another embodiment, contact between the superior surface of the lateral mass plate **2620** and the engaging rod **2716** causes the engaging rod **2716** to slightly retract while the plate **2620** is moved into the engagement seat **2714**. Once the lateral mass plate **2620** is seated, the third bore **2602** preferably registers with the engaging rod **2716**, whereby the urging force causes the engaging rod **2716** to automatically engage the third bore **2602**.

During the surgical procedure, the natural or artificial facet joint spacer or inter-facet joint spacer **2610** is inserted into the distracted facet joint as described in detail above. Upon the natural or artificial facet joint spacer or inter-facet joint spacer **2610** being satisfactorily inserted in the facet joint, the user preferably actuates the switch **2708** to disengage the engaging rod **2716** from the third bore **2602**. The surgeon then draws the tool **2700** away from the facet joint, whereby the lateral mass plate **2620** slides out of the received area and is guided by the slots **2712**. The lateral mass plate **2620** is then anchored into the vertebral body as discussed above.

In still other embodiments, some other structure can be employed to resist movement of the seated bone screw within the first bore. Referring to **FIGS. 41A** and **41B**, in some embodiments a cam **2824** can be rotatably associated with the lateral mass plate **2820** so that the first bore **2830** can be selectably obstructed or unobstructed, thereby allowing a bone screw **2840** to be received within the first bore **2830**, or resisting movement of the bone screw **2840** seated within the first bore **2830**. As shown in **FIG. 41A**, the cam **2824** can have a shape such that at a first position the surface **2828** of the cam is approximately flush with the first bore **2830**, thereby allowing a bone screw **2840** to pass through the first bore **2830**. Rotated to a second position (**FIG. 41B**), a protruding portion **2826** of the surface of the cam **2824** can extend across at least a portion of the first bore **2830**, thereby blocking a bone screw **2840** seated within the first bore **2830** and preventing the bone screw **2840** from backing out of the first bore **2830**. The cam **2824** can include features **2831** (e.g., indentations) that can allow the cam to be grasped with a tool (not shown), and thus rotated to the desired position. As shown, the cam **2824** is positioned within a slot of the lateral mass plate **2820** so that the cam does not protrude undesirably from the surface of the lateral mass plate **2820**.

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Except as otherwise noted above, the embodiment shown in **FIGs. 22A-24B** is similar to the embodiment shown in **FIGs. 41A-41B**.

A further embodiment of an implant **2900** in accordance with the present invention is shown in **FIGs. 42A-42G**. The implant **2900** resembles implants as shown in **FIGs. 22A-25A** in that the natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **2910** has limited freedom of movement relative to the lateral mass plate **2920**. As can be seen, a hinge **2922** connects the natural or artificial facet joint spacer or inter-facet joint spacer **2910** with the lateral mass plate **2920**, allowing the natural or artificial facet joint spacer or inter-facet joint spacer to pivot up and down relative to a plane of the lateral mass plate **2920**. However, in other embodiments the natural or artificial facet joint spacer or inter-facet joint spacer **2910** can be connected with the lateral mass plate **2920** by way of a spheroidal joint arrangement (as described above) or by way of some other structure. An inferior surface **2915** of the natural or artificial facet joint spacer or inter-facet joint spacer **2910** includes a plurality of cleats (also referred to herein as protrusions) **2986** extending from the inferior surface **2915**. In one example as seen in **Fig 42A** the cleats point in a direction that is opposed to the direction of insertion of the natural or artificial joint in the facet joint in order to ease the insertion step and to aid in preventing the natural or artificial facet joint spacer or inter-facet joint spacer from backing out of the facet joint. Additionally the cleats or protrusions have, in one embodiment, a thickness that is less than the thickness of the natural or artificial facet joint spacer or inter-facet joint spacer defined between a superior surface of the natural or artificial facet joint spacer or inter-facet joint spacer and an inferior surface of a natural or artificial facet joint spacer or inter-facet joint spacer. The plurality of cleats **2986** can penetrate or grip a superior facet of a lower vertebra of the targeted facet joint, thereby reducing slippage of the natural or artificial facet joint spacer or inter-facet joint spacer **2910** relative to the superior facet. The cleats **2986** do not directly restrict the inferior facet of an upper vertebra of the targeted facet joint from moving along the superior surface **2913** of the natural or artificial facet joint spacer or inter-facet joint spacer **2910**. The cleats **2986** can further promote bone growth by roughing the surface, which can provide beneficial results where an increase in surface contact resulting in a reduction of slippage is desired. In a preferred embodiment the natural or artificial facet joint spacer or inter-facet joint spacer **2910** can include an inferior surface **2915** connected with the hinge **2922** and formed of a light-weight, bio-compatible material having a desired strength, such as titanium, titanium alloys, aluminum, aluminum alloys, medical grade stainless steel, etc. Such a structure is also referred to herein as an inferior shim **2980**. As shown, a substantial portion of the natural or artificial facet joint spacer or inter-facet joint spacer **2910** including the superior surface **2913** can be formed of a biocompatible polymer, such as described below. Such a substantial portion is also referred to herein as a superior shim **2982**. Such a material is radiolucent, and can have a desired smoothness and reduced compressive strength relative to the inferior surface **2915** such that the superior

surface **2913** of the natural or artificial facet joint spacer or inter-facet joint spacer **2910** allows for a desired slippage relative to the inferior facet of the facet joint. A superior surface **2913** having a reduced compressive strength and an increased elasticity relative to a bony structure of the spine. The superior shim **2982** can be molded onto the inferior shim **2980** to form the natural or artificial facet joint spacer or inter-facet joint spacer **2910**, or the superior shim **2982** can be adhesively fastened to the inferior shim **2980**, interference fit with optional protuberances of the inferior shim **2980**, etc. One of ordinary skill in the art will appreciate the different techniques for fixedly connecting a superior shim **2982** with the inferior shim **2980**.

It is also to be understood that the inferior shim can be comprised of a rigid material while the superior shim can be comprised of a more compliant and/or compressible material. Thus the inferior shim can carry the load experienced in the facet joint while the superior shim can be more compliant. The natural or artificial facet joint spacer or inter-facet joint spacer can, for example, be comprised of one material that has been formed to have a gradient of stiffness from more stiff in the area of the inferior shim to less stiff and more compliant in the area of the superior shim. For example a PEEK polymer material as described below can be formed in the area of the inferior shim with fillers that increase the stiffness and strength of the material while the PEEK polymer in the area of the superior shim does not have such fillers and is thus more compliant.

In a preferred embodiment, the cleats **2986** of the implant **2900** can extend from the inferior surface **2915** to have a sawtooth shape and arrangement to resist movement in a generally posterior direction away from the facet joint (i.e., toward the lateral mass plate **2920** as shown) and further to resist movement in a lateral direction relative to the facet joint. However, the cleats **2986** need not necessarily be sawtooth in shape and arrangement. For example, the cleats **2986** can have a conical shape, a pyramid shape, a curved shape, etc. Further, as shown particularly in **FIG. 42C** four cleats **2986** extend from the inferior surface **2915**. In other embodiments, any number of cleats **2986** can be provided, the cleats **2986** being similarly sized and shaped, or varying in size and shape. In reflection on the teachings contained herein, one of ordinary skill in the art will appreciate the myriad different shapes with which the cleats **2986** can be formed. The cleats **2986** can vary in performance and technique for implantation with shape and number; however, the present invention is meant to encompass all such variations.

The implant **2900** can further optionally include plate cleats **2988** extending from a surface of the lateral mass plate **2920** substantially contacting the bony structures of the spine (e.g., the lateral mass). The plate cleats **2988** can help anchor the lateral mass plate **2920** in position either to assist in resisting shifting as a bone screw **2940** is associated with the bony structure, or as an adjunct to the bone screw **2940**. Surface roughening caused by the plate cleats **2988** can further promote bone growth near and/or integrally with the lateral mass plate **2920**. As shown particularly in **FIG. 42C** there are four plate cleats **2988**, each

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plate cleat **2988** having a conical structure. However, as above the plate cleats **2988** can vary in size, number and shape. For example, the plate cleats **2988** can have a saw-tooth shape, a pyramid shape, a curved shape, etc.

Referring to **FIGs. 42D** through **42G**, a bone screw **2940** of the implant **2900** can be arranged in a bore **2930** so that the bone screw **2940** and bore **2930** permit a relative degree of freedom of movement resembling a ball-in-socket joint. Such an arrangement can allow for flexibility in fastening the implant **2900** to a bony structure, thereby allowing a surgeon to avoid diseased or fragile bony structures, fastening the implant **2900** to more durable, healthy bony structures. The bone screw **2940** can swivel within the bore **2930** toward or away from the natural or artificial facet joint spacer or inter-facet joint spacer **2910** and/or from side-to-side relative to the natural or artificial facet joint spacer or inter-facet joint spacer **2910**.

When the bone screw **2940** is arranged as desired a retaining plate **2924** (**FIG. 42B**) can be attached to the lateral mass plate **2920** to resist backing out of the bone screw **2940**, similar to the functioning of features as shown in previous embodiments. As can be seen in **FIG. 42B**, retaining plates **2924** can have a projection **2925** that fits in a recess **2927** of the lateral mass plate **2920** in order to prevent rotation of the retaining plate **2924** once bone screw **2940** is tightened against retaining plate **2924**.

Referring to **FIG. 43**, in still further embodiments, implants in accordance with the present invention can have both an inferior surface **3015** and a superior surface **3013** having cleats **3086** extending therefore. Such embodiments can be employed, for example, to fuse the facet joint. The cleats **3086** can resist relative movement of the inferior and superior facets, and can further promote bone growth through roughening of the facet surface, thereby promoting fusion of the facet joint. The natural or artificial facet joint spacer (or insert) or inter-facet joint spacer (or insert) **3010** can be formed from a light-weight, high strength, biocompatible material such as titanium, titanium alloys, aluminum, aluminum alloys, medical grade stainless steel, etc. Alternatively, the natural or artificial facet joint spacer or inter-facet joint spacer **3010** can be formed from a biocompatible polymer, as described below, or the natural or artificial facet joint spacer or inter-facet joint spacer **3010** can comprise inferior and superior shims (not shown) fixedly connected and formed of the same or different materials. Upon reflection of the teachings herein, one of ordinary skill in the art will appreciate the different ways in which the natural or artificial facet joint spacer or inter-facet joint spacer **3010** can be formed.

As described above in reference to **FIGs. 42A-G**, the cleats **3086** are saw-tooth in shape and arrangement, but alternatively can have some other shape and/or arrangement. For example, the cleats **3086** can have a pyramidal shape, a curved shape, a conical shape, etc. Further, the shape, size and arrangement for cleats **3086** of the inferior surface **3015** can be different or the same from cleats **3086** of the superior surface **3013**. The shape, size, and arrangement of the cleats **3086** can be chosen based on the

location of implantation, the preferences of the surgeon, the physical condition of the target facet joint, etc.

FIG. 40 is a flow chart of an embodiment of a method in accordance with the present invention for implanting an implant as described in **FIGs. 34A** through **39**.

FIG. 44 illustrates a side view of a distractor tool in accordance with one embodiment of the present invention. As shown in **FIG. 44**, the distractor tool **203** preferably includes a handle portion **202**, an arm portion **204**, and a distractor head portion **206**. In particular, the handle portion **202** preferably includes a first handle **202A** and a second handle **202B**. The proximal ends of each handle **202A**, **202B** preferably include finger loops **212A** and **212B**, respectively. The handles **202A** and **202B** are coupled to one another at a pin **208**. In a preferred embodiment, the first handle **202A** is moveable whereas the second handle **202B** is stationary with respect to the first handle **202A**. In another embodiment, the second handle **202B** is able to be pivotably rotated with respect to first handle **202A** about pin **208**. Alternatively, both handles are movable with respect to one another about pin **208**.

As shown in the embodiment in **FIG. 44**, the arm portion **204** has a first arm **204A** and a second arm **204B**. The arms **204** are oriented longitudinally along the X-axis. The upper arm **204B** is preferably attached to the second handle **202B**. However, the second arm **204B** can alternatively be attached to the first handle **202A**. In the embodiment in **FIG. 44**, the first arm **204A** and the second handle **202B** are of one formed piece. Alternatively, the first arm **204A** and the second handle **202B** are two separate pieces which are coupled together.

As stated above, the first handle **202A** is rotatable about pin **208**, whereby the pin **208** is preferably located between the midpoint and a distal end of the handle **202A**. In one embodiment shown in **FIG. 3A** and **3B**, a proximal end of the first arm **204A** is coupled to the distal end of the first handle **202A** at pin **210**. In another embodiment, the distal end of the handle **202A** is coupled to an intermediate link which couples the handle **202A** to the first arm **204A**.

The first handle **202A** is preferably moveable about pin **208** between an non-distracted position, as shown in **FIG. 44**, and a distracted position as shown in **FIG. 45**. As shown in **FIG. 44**, the first handle **202A** is oriented at angle α with respect to the X-axis. In addition, the second handle **202B** is oriented at angle β with respect to the X-axis. In **FIG. 44**, the angle α of the first handle **202A** in the non-distracted position is greater than the angle ϕ of the first handle **202A** in the distracted position. It is preferred that, as the handles **202A**, **202B** are squeezed together, the tool **203** actuates from an non-distracted position to a distracted position.

When the handles **202A**, **202B** of the tool **203** are squeezed together, the clockwise rotational movement of the handle **202A** about the pin **208** causes the distal end of the handle **202A** to move the first arm **204A** longitudinally along the positive X-axis (**FIG. 45**). In contrast, when the handle **202** is released

or when manually actuated to the non-distracted position, the counter-clockwise rotational movement of the handle **202A** causes the distal end of the handle **202A** to move the first arm **204A** in the opposite direction, along the negative X-axis (**FIG 44**). The longitudinal movement of the first arm **204A** along the X-axis causes the distraction head **206** to actuate and thus separate adjacent facets apart to allow implantation of the implant.

The distal ends of the first and second arms **204A**, **204B** are coupled to the distraction head **206** as shown in **FIGs. 44** and **45**. The distraction head **206** preferably includes a first distraction head component **206A** and a second distraction head component **206B**. In one embodiment, the distal end of the first arm **204A** is coupled to the first distraction head component **206A** and the first distal end of the second arm **204B** is coupled to the second distraction head component **206B**. In another embodiment, the distal end of the first arm **204A** is coupled to the second distraction head **206B** and the distal end of the second arm **204B** is coupled to the first distraction head **206B**. Since the first arm **204A** is attached to the first distraction head component **206A**, the movement of the first arm **204A** along the X-axis preferably causes the first distraction head component **206A** to also move along the X-axis. The second head component **206B** is preferably fixed to the second arm **204B**. Therefore, the movement of the arm **204** along the positive X-axis causes the first head component **206A** to move preferably away from the second head component **206B**. The first head component **206A** and the second head component **206B** preferably separate the adjacent facets apart between 1.5 and 2.5 mm to accommodate the thickness of the natural or artificial joint facet or inter-facet joint spacer of the implant. However, other distances are contemplated and are not limited to that described above.

In the preferred embodiment, the distal portion of the distraction head extends substantially perpendicular to the arms **204A**, **204B**, as shown in **FIGs. 44** and **45**. In another embodiment, the superior and inferior surfaces of the distraction head extend at an angle other than 90 degrees from the arms **204A** and **204B**. In the preferred embodiment shown in **FIGs. 44** and **45**, the head components **206A**, **206B** of the distraction head **206** are oriented such that the leading edge **230** extends in the negative Y direction. Alternatively, the distraction head **206** is oriented such that the leading edge faces the positive Y direction. However, it is contemplated that the distraction head **206** can be oriented to extend from the arm **202** such that the leading edge faces the Z direction, as shown in **FIGs. 48A** and **48B**. It is contemplated that the leading edge **230** of the distraction head **206** of the present invention can face any direction with respect to the arms **204** and the handles **202** including the negative Z direction.

The tool **203** of the present invention is preferably made from a medical grade metal. For example, the tool **203** can be made of titanium, stainless steel, an alloy or any other material which provides the tool **203** with a sufficient amount of strength to distract the adjacent facets apart during the implantation

process. In one embodiment, the distraction head **206** is removable from the distal ends of arms, such that different sized distraction heads can be used with the same tool. This feature would allow the surgeon to replace the distraction head with one of a different size for a different inter-cervical facet joint without having to use a different tool. In another embodiment, the distraction head **206** is mounted to the arms **204** of the tool **203**, whereby the upper head component **206A** is welded to the lower arm **204A** and the lower head component **206B** is welded to the upper arm **204B** or vice versa. Any other appropriate method of attaching the distraction head **206** to the arms **204** is contemplated.

It is preferred that the tool **203** includes a movement limitation mechanism. The mechanism preferably limits the amount of distraction between the first and second head components **206A**, **206B** when the handles **202** are actuated. As shown in **FIGs. 44** and **45**, the proximal end of the first arm **204A** preferably has a wedge-shaped portion **216**. In addition, the second arm **204B** includes a correspondingly shaped slot **218** which receives the wedged portion **216** during movement of the wedged portion **216** in the positive X direction. The slot **218** limits longitudinal movement of the first arm **204A** along the X-axis when the handles **202** are squeezed. This, in effect, limits the distance that the head components **206A**, **206B** separate in distracting the facets apart from one another during the implantation procedure. Alternatively, any other mechanism is contemplated to limit movement of the distraction head **206** and is not limited to the wedged portion **216** and corresponding slot **218** of the present tool. It should be noted that the movement limitation mechanism is alternatively not incorporated in the tool of the present invention.

FIG. 46A illustrates a perspective view of the distraction head **206** in a distracted position in accordance with one embodiment. **FIG. 46B** illustrates a perspective view of the distraction head **206** in **FIG. 46A** in a non-distracted position. As shown in **FIGs. 46A** and **46B**, the distraction head **206** preferably includes the first head component **206A** having a proximal portion and a distal portion as well as the second head component **206B** having a proximal portion and a distal portion. As shown in **FIGs. 46A** and **46B**, the first head component **206A** includes an engagement slot **222A** at the proximal end. In addition, the second head component **206B** includes a pass-through slot **222B** which is aligned with the engagement slot **222A**. The engagement slot **222A** of the first head component **206A** preferably receives and mounts to the distal end of the first arm **204A**. The first arm **204A** preferably extends through the pass-through slot **222B** in the second head component **206B** to allow the arm **204A** to freely move the first head component **206A** without interfering with the second head component **206B**. The proximal portion of the second distraction head **206B** is attached to the distal end of the second arm **204B**. The second arm **204B** is preferably mounted to the underside **240** of the second head component **206B**, whereby the second arm **204B** is located adjacent to the first arm **204A**. It should be noted that the above description of the

head components is preferred and can have any other appropriate configuration to allow distraction in accordance with the present invention.

The distal portion of both first and second distraction heads **206A**, **206B** includes leading edges, shown as **230A** and **230B**, which are used to penetrate the facet joint to insert the distraction head **206** therein. The distal portion of the first and second head components, as shown in **FIG. 46A**, include several fingers which are shown alternately arranged. In particular, the first distraction head **206A** is shown to have two fingers **224A** whereas the second distraction head **206B** is shown to have three fingers **224B**. In another embodiment, the upper and lower distraction heads **206A**, **206B** have a greater or fewer number of fingers than that shown in **FIG. 46A**, including only one finger each. The fingers **224A**, **224B** together form an overall rounded leading edge **230** of the distraction head **206** as shown in **FIG. 46B**. In another embodiment, the leading edges **230** of the fingers do not form a rounded leading edge, but can form any other shape.

As shown in **FIGs. 46A** and **46B**, the second head component **206B** includes finger slots **232** which receive the fingers **224A** of the first head component **206A** when the distraction head **206** is in the non-distracted position (**FIG. 46B**). In the non-distracted position, as shown in **FIG. 46B**, the first head component **206A** and the second head component **206B** are co-planar, whereby the fingers **224A** and **224B** are preferably inter-digitated. The co-planar head components provide a height dimension or thickness which allows the distraction head **206** to be easily inserted into the facet joint. Upon the handles **202** being squeezed, the first head component **206A** is forced away from the second head component **206B**, thereby causing the first set of fingers **224A** from sliding out of the finger slots **232** of the second head component **206B**. The first head component **206A** thus moves apart from the second head component **206B** until the desired distance between the head components is achieved. As shown in **FIG. 46A**, the fingers **224A** of the first head component **206A** are separated from the fingers **224B** of the second head component **206B** and is no longer co-planar in the distracted position.

As shown in **FIG. 46A**, the fingers **224A**, **224B** each have a superior surface **226A**, **226B**, as well as an inferior surface **228A**, **228B**. In one embodiment, the leading edge **231A**, **231B** of the fingers **224A**, **224B** are rounded or curved, as shown in **FIGs. 46A** and **46B**. In another embodiment, the leading edges of the fingers **224A**, **224B** are sharpened.

In one embodiment, the superior surfaces **226A**, **226B** of the distraction head components **206A**, **206B** mate with the inferior facet of the vertebral body when the distraction head **206** is inserted into the facet joint. Additionally, in one embodiment, the inferior surfaces **228A**, **228B** of the distraction heads **206A**, **206B** mate with the superior facet of the vertebral body. However, it is contemplated that the tool **203** can be oriented upside down such that the superior surface of the head **206** mates with the superior

facet and the inferior surface of the head **206** mates with the inferior facet of the vertebral bodies.

As shown in **FIGs. 46A** and **46B**, the distal portion of the distraction head **206** is relatively flat such that the superior and inferior surfaces **226**, **228** of the head components **206A**, **206B** are generally parallel with one another and have a uniform thickness. In another embodiment, the inferior and superior surfaces taper toward each other at the leading edge **231A**, **231B**. The head components **306A**, **306B** can alternatively be shaped to contour the shapes of the facets. The facet itself is somewhat shaped like a ball and socket joint. Accordingly, as depicted in **FIGs. 47A** and **47B**, the distraction head **306** can have a convex superior surface **326** and a concave inferior surface **328**. The curved superior and inferior surfaces preferably taper toward each other at the leading edge **322A**, **322B** to facilitate insertion, while the remainder of the distraction head has a uniform thickness.

In addition, as shown in **FIG. 47B**, the individual head components each can have a concave and/or convex shape. In another embodiment, one of the superior and inferior surfaces **326A**, **326B**, **328A**, **328B** have a convex or concave shape, whereas the other surface is planar and does not have a curved shape. The superior and inferior surfaces of the distraction head **306** thus preferably contour the respective facets of the joint. The contour of the superior and/or inferior surfaces of the head **306** allows the upper and lower head components to apply a relatively constant force to the superior and inferior facets while the tool is actuated to the distracted position. In addition, the contoured shaped of the distraction head **306** along with its fingers allow the head components to obtain a better grip with their respective facets during the distraction procedure.

FIGs. 48A and **48B** illustrate another embodiment of the tool having the distraction head in an alternative orientation than that shown in **FIGs. 44** and **45**. As shown in **FIG. 48A**, the tool **403** includes the handle portion **402**, the arm section **404** and the distraction head **406**. As shown in **FIG. 48A**, the arm portion **404** is oriented along the X-axis. However, unlike the tool **203** described in **FIGs. 44** and **45**, the distraction head **406** extends from the arm portion **404** such that the leading edge **430** faces in the positive Z direction. In the embodiment shown in **FIG. 48A**, the distraction head **406** extends from the arm portion along the positive Z direction at approximately a 90 degree angle with respect to the arm **404**. However, the distraction head **406** can be oriented to extend from the arm **404** along the negative Z direction or at any other angle besides 90 degrees.

In operation, actuation of the handle **402A** causes the arm **404A** to move along the X axis to actuate the distraction head **406** as shown in **FIG. 48B**. As shown in **FIG. 48B**, the leading edges **430A** and **430B** of the first and second head components **406A**, **406B** are preferably tapered. The orientation of the leading edge **230** in the Z direction allows the tool **403** to be oriented in a different manner than the tool **203** in **FIGs. 44** and **45** during the implantation procedure. This alternative orientation of the tool **403** may

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be advantageous to distract facets along different portions of the spine which require the tool **403** to be oriented at a different angle. Additionally, the individual tastes of each physician may prefer the alternative orientation of the tool **403** over the orientation of the head **206** in the embodiment in **FIGs. 44** and **45**.

FIGs. 49A – 49C illustrate one method of distracting adjacent facets in accordance with the tool of the present invention. **FIG. 49D** illustrates a flow chart of the method of implantation in accordance with one embodiment of the invention. The facet joint **60** is initially accessed as in step **602**, as shown in **FIG. 49A**. A sizing tool can be inserted into the facet joint **60** to select the appropriate size of implant to be inserted as in step **604**. In one embodiment, the sizing tool is a unit separate from the tool **203** of the present invention. In another embodiment, the tool **203** of the present invention has a sizing gauge to allow the surgeon to determine what size of implant is to be inserted into the facet joint as discussed in relation to **FIG. 49**. As shown in **FIG. 49A**, the leading edge **231** of the tool **203** is then inserted into the entrance of the facet joint **60**. The leading edge **231** of the tool **203** is then urged into the facet joint **60** until the distraction head **206** is sufficiently displaced within the facet joint **60** and between the superior and inferior facets **56, 58**, as in **FIG. 49B**. In **FIGs. 49A – 49C**, the tool **203** accesses the joint from a superior approach (i.e. upside down). However, it should be noted that the tool **203** can alternatively access the facet joint from an inferior (e.g. right side up) or lateral (e.g. sideways) approach.

Once the distraction head **206** is inserted, the physician squeezes the handles **202A, 202B** together, whereby the distraction head components **206A** and **206B** separate from one another and distract the facet joint and surrounding tissue in order to facilitate insertion of the implant, as in step **604 (FIG. 49C)**. Once the adjacent facets are distracted apart the desired distance, the tool **203** is then removed from the joint, thereby leaving the adjacent facets apart from one another. The distracted tissue surrounding the facets slowly contract, thereby leaving time for the physician to urge the natural or artificial facet joint spacer or inter-facet joint spacer **104** of the implant between the facets into the facet joint, as in step **606**.

Once the natural or artificial joint is inserted, the lateral mass plate of the implant is pivoted downward about the hinge toward the lateral mass or to the lamina, as in step **608**. Once the lateral mass plate is positioned, or prior to the positioning of the lateral mass plate, a bore can be drilled into the bone to accommodate the bone screw. The screw is then placed through the bore and secured to the bone to anchor the natural or artificial facet joint spacer or inter-facet joint spacer in place as in step **610**. In order to lock the bone screw and position of the natural or artificial facet joint spacer or inter-facet joint spacer and lateral mass plate in place, the locking plate is positioned over the lateral mass plate, as in step **612**. The keel located adjacent to the locking plate can preferably self-cut a groove into the bone to lock the keel and anchor the implant, as in step **614**. The locking plate is then fastened to the lateral mass plate with the screw through the bore, as in step **616**. This method is then repeated for any other facet joints in the spine,

as in step 618.

FIG. 50A and 50B illustrate another embodiment of the tool of the present invention. The embodiment shown in **FIGs. 50A and 50B** includes a distraction head **806** which is configured to distract adjacent facets of the vertebral bodies and simultaneously allow insertion of the implant into the facet joint.

5 The tool **803** shown in **FIGs. 50A and 50B** includes the handle portion **802**, the arm portion **804** as well as the distraction head **806**.

As shown in **FIGs. 50A and 50B**, the fingers of the distraction head **806** are offset and adjacent to the arms **804A** and **804B** of the tool **803**. As shown in **FIGs. 50A and 50B**, the distraction head **806** includes a leading edge **808** which is shown facing the negative Y direction as well as insertion edges
10 **811A, 811B** which face the positive Y direction. The insertion edges **811A, 811B** are preferably located on the opposite end of the head **806** from the leading edge **808**. The leading edge **808** is configured to be inserted into the facet joint to distract the adjacent facets apart as stated above. The insertion end **811A, 811B**, upon distraction, allows the implant to be inserted into the facet joint while the tool **203** is simultaneously distracting the facets apart. The insertion edges **811A, 811B** of the head components
15 **806A, 806B**, respectively, move apart as the head components **806A, 806B** are distracted. This creates an insertion conduit **824** between (**FIG. 50B**) the first and second head components **806A, 806B**. The insertion conduit **812** has a height distance, D , which provides adequate clearance between the inferior surface **822** of the first head component **806A** and the superior surface **824** of the second head component
20 **804B** to allow the implant to be inserted therethrough. As stated above, the distraction head **806** is offset and located adjacent to the arms **804** and handle **802** of the tool **803**, whereby the location of the head **806** provide ample room to insert the implant therethrough.

In operation, upon the distraction head **806** being inserted into the facet joint, the handles **802** are squeezed together to cause the distraction head components **806** to separate, thereby distracting the facets until the insertion conduit **812** is at the desired height dimension D . The desired height dimension, D , will
25 depend on several factors, such as size of the natural or artificial inter-facet joint or inter-facet joint spacer, the thickness of the fingers of the head components, and the location of the facet joint (e.g. cervical, thoracic, lumbar). It is preferred that the height dimension D be between 1.5 and 2.5 mm, although other dimensions are contemplated. The height dimension D can be measured by a distraction gauge, as stated below, to achieve the desired height dimension.

30 Upon achieving the desired height dimension, D , the natural or artificial insertion joint of the implant is inserted into the insertion conduit **812** via the insertion ends **811A, 811B**. Considering that the insertion conduit **812** is in communication with the facet joint of the spine, the implant is able to slide through the conduit **812** into the facet joint. Upon the natural or artificial inter-facet joint or inter-facet

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joint spacer being secured in the facet joint, the distraction head **806** can then be removed from the facet joint, thereby leaving the implant inserted therein. The implant can then be anchored as discussed above.

This embodiment allows the physician to maintain the distraction distance between the facets while inserting the implant. This embodiment, including the sizing gauge discussed below, can allow the physician to size, distract, and insert the implant using one tool. It should be noted that although the embodiment in **FIG. 49A** has the lead and insertion edges of the distraction head facing in the Y direction, the lead and insertion edges can face the Z direction or any other direction.

In one embodiment shown in **FIG. 51**, the distraction tool **903** can include a sizing mechanism in accordance with one embodiment of the present invention. As shown in **FIG 51**, the distraction gauge **950** is coupled to one of the handles **902A** and **902B**. The other handle can include a flag **952** or pointer for indicating a distraction height measurement on the distraction gauge **950**. Thus, as the handle **902A** is urged toward the distraction position, the distraction gauge **950** slides past the flag **952**, along with indicia indicating the increasing distraction height, *D*, between the distraction head components **906A** and **906B**. In one embodiment, the distraction gauge **950** is configured to provide the amount of distance between the inferior surface of the first head component **906A** and the superior surface of the second head component **906B** (i.e. the insertion conduit). In another embodiment, the distraction gauge **950** can be configured to include the thickness of the first and second head components and thereby indicate the total distraction distance between adjacent facets.

In one embodiment, the tool **903** includes a spring mechanism to urge the handles **902A**, **902B** apart toward the non-distracted position. For example, a leaf spring **912** can be configured along the inner surfaces of the handles **902A**, **902B** to provide an outward bias against the handles **902A**, **902B**. In another example, a spring can be positioned between the interior wall of the slot **918** and the wedge portion **916** of the arm **904A** to urge the wedged portion **916** and thus the handle **902A** toward the non-distracted position.

Additionally, or alternatively, the tool **903** can include a locking mechanism to lock the tool **903** in a desired position. For example, the locking mechanism can include a threaded rod **914** which is coupled to one of the handles **902A**, **902B** at a pivot point **916**, whereby the rod **914** freely passes through a through-hole in the other of the first and second handles **902A**, **902B**. The rod **914** includes a turning bolt **922** on the outer surface of the handle **904A** which limits movement of the handles **902** which is caused by the force of the spring **910**. As the handle **902A** is urged closed, the threaded rod **914** passes through the through-hole and pivots to follow the arcing travel of the handle **902A**. A distraction stop **920** can be positioned along the threaded rod **914** and sized such that the distraction stop **920** blocks the free travel of the threaded rod **914**, thereby preventing further movement of the handle **902** and limiting the distraction

height. In one embodiment, the distraction stop **920** is fixed in position along the threaded rod **914**, however, in other embodiments the distraction stop **920** can be adjustably positionable along the threaded rod **914** to allow the maximum distraction height to be adjusted.

5

MATERIALS FOR USE IN IMPLANTS OF THE PRESENT INVENTION

As alluded to above, and as described in further detail as follows, in some embodiments, the implant, and components of the implant (i.e., a lateral mass plate, a bone screw, a locking screw, etc.) can be fabricated from medical grade metals such as titanium, stainless steel, cobalt chrome, and alloys thereof, or other suitable implant material having similar high strength and biocompatible properties. Additionally, 10 the implant can be at least partially fabricated from a shape memory metal, for example Nitinol, which is a combination of titanium and nickel. Such materials are typically radiopaque, and appear during x-ray imaging, and other types of imaging. Implants in accordance with the present invention, and/or portions thereof (in particular a natural or artificial facet joint spacer or inter-facet joint spacer) can also be fabricated from somewhat flexible and/or deflectable material. In these embodiments, the implant and/or 15 portions thereof can be fabricated in whole or in part from medical grade biocompatible polymers, copolymers, blends, and composites of polymers. A copolymer is a polymer derived from more than one species of monomer. A polymer composite is a heterogeneous combination of two or more materials, wherein the constituents are not miscible, and therefore exhibit an interface between one another. A polymer blend is a macroscopically homogeneous mixture of two or more different species of polymer. 20 Many polymers, copolymers, blends, and composites of polymers are radiolucent and do not appear during x-ray or other types of imaging. Implants comprising such materials can provide a physician with a less obstructed view of the spine under imaging, than with an implant comprising radiopaque materials entirely. However, the implant need not comprise any radiolucent materials.

One group of biocompatible polymers is the polyaryletherketone group which has several members 25 including polyetheretherketone (PEEK), and polyetherketoneketone (PEKK). PEEK is proven as a durable material for implants, and meets the criterion of biocompatibility. Medical grade PEEK is available from Victrex Corporation of Lancashire, Great Britain under the product name PEEK-OPTIMA. Medical grade PEKK is available from Oxford Performance Materials under the name OXPEKK, and also from CoorsTek under the name BioPEKK. These medical grade materials are also available as reinforced polymer resins, 30 such reinforced resins displaying even greater material strength. In an embodiment, the implant can be fabricated from PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex. Other sources of this material include Gharda located in Panoli, India. PEEK 450G has the following approximate properties:

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Property	Value
Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
5 Tensile Strength	97 MPa
Modulus of Elasticity	3.5 GPa
Flexural Modulus	4.1 GPa

10 PEEK 450G has appropriate physical and mechanical properties and is suitable for carrying and spreading a physical load between the adjacent spinous processes. The implant and/or portions thereof can be formed by extrusion, injection, compression molding and/or machining techniques.

It should be noted that the material selected can also be filled. Fillers can be added to a polymer, copolymer, polymer blend, or polymer composite to reinforce a polymeric material. Fillers are added to modify properties such as mechanical, optical, and thermal properties. For example, carbon fibers can be added to reinforce polymers mechanically to enhance strength for certain uses, such as for load bearing devices. In some embodiments, other grades of PEEK are available and contemplated for use in implants in accordance with the present invention, such as 30% glass-filled or 30% carbon-filled grades, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to unfilled PEEK. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to have enhanced compressive strength and stiffness, and a lower expansion rate relative to unfilled PEEK. Carbon-filled PEEK also offers wear resistance and load carrying capability.

As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable, have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. As mentioned, the implant can be comprised of polyetherketoneketone (PEKK). Other material that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics. Reference to appropriate polymers that can be used in the implant can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3,

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2002, entitled "Bio-Compatible Polymeric Materials." Other materials such as Bionate7, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

5 The foregoing description of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to practitioners skilled in this art. The embodiments were chosen and described in order to explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with
10 various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalents.

WHAT IS CLAIMED:

1. A facet joint implant that addresses spinal stenosis and other ailments of the spine while maintaining mobility of the facet joint, the implant comprising:
 - an anchoring plate;
 - 5 a facet joint spacer; and
 - an articulation joint connecting the anchoring plate to the facet joint spacer.

2. The implant of claim 1, wherein the articulation joint is one of a hinge, a ball-and-socket joint, and bendable material.

- 10 3. The implant of claim 1, wherein the articulation joint includes:
 - a cavity with the anchoring plate; and
 - a ball-shaped end extending from the facet joint spacer and positioned in the cavity of the anchoring plate.

- 15 4. The implant of claim 1, further comprising:
 - a locking screw;
 - a bone screw;
 - wherein:
 - 20 the anchoring plate further includes a first bore and a second bore;
 - the bone screw is receivable within the first bore; and
 - the locking screw is receivable within the second bore.

- 25 5. The implant of claim 4, wherein the locking screw has a head that blocks the bone screw from at least one of a backward displacement and a rotational displacement.

6. The implant of claim 4, wherein the locking screw further comprises a chisel-point end, wherein the chisel point end self-cuts the locking screw into the vertebra.

- 30 7. The implant of claim 1, wherein when said articulation joint allows said facet joint spacer is to swivel and tilt relative to the anchoring plate.

8. The implant of claim 1 wherein said facet joint spacer is shaped to accommodate and fit between superior and inferior portions of a facet joint.

9. The implant of claim 1 wherein the anchoring plate is adapted to anchor to the lateral mass.
10. The implant of claim 1 wherein the facet joint spacer is adapted to distract the spinal facet joint
5 and allow mobility of the spinal facet joint.
11. The implant of claim 1 including said facet joint spacer having a convex surface adapted to mate with the facet joint.
- 10 12. The implant of claim 1 wherein:
the facet joint spacer includes a wedge-shaped front end adapted to allow the front end to be wedged into a facet joint, wherein the facet joint spacer distracts the facet joint and increases the foraminal area, without eliminating mobility of the facet joint.
- 15 13. A facet joint implant adapted to correct spinal stenosis and other ailments of the spine, the implant comprising:
a first facet joint spacer adapted to be positioned within a first facet joint formed by two adjacent spinal vertebrae of a first level;
a second facet joint spacer adapted to be positioned within a second facet joint formed by the
20 two adjacent spinal vertebrae of the first level; and
a collar joining the first facet joint spacer with the second facet joint spacer.
- 25 14. The facet joint implant as in claim 13 wherein the collar is connected flexibly with the first facet joint spacer by a first hinge and the collar is connected flexibly with the second facet joint spacer by a second hinge.
15. The facet joint implant as in claim 13 wherein the collar is connected flexibly with the first facet joint spacer and the collar is connected flexibly with the second facet joint spacer.
- 30 16. The facet joint implant as in claim 13 wherein the collar further comprises a first bore positioned adjacent to the first facet joint spacer, and a second bore positioned adjacent to the second facet joint spacer, the first bore capable of accepting a first bone screw and the second bore capable of accepting a second bone screw, adapted to secure the implant to the vertebra.

17. The facet joint implant as in claim 13 wherein the collar can be bent to conform to the anatomy of a patient's cervical spine.

18. The facet joint implant as in claim 16 including a first locking device positioned to prevent the displacement of the first bone screw, and a second locking device positioned to prevent the displacement of the second bone screw.

19. The facet joint implant as in claim 13 wherein a surface of the first facet joint spacer and a surface of the second facet joint spacer are convex to approximate the shape of a cervical facet joint.

20. The facet joint implant as in claim 13 wherein a first distal end of the first facet joint spacer and a second distal end of the second facet joint spacer are tapered to facilitate insertion into a cervical facet joint.

21. The facet joint implant as in claim 1 wherein the implant is adapted to be implanted without resection of bone.

22. A facet joint implant of claim 1 comprising:
a bone screw;
a locking screw;
the anchoring plate receives the bone screw and the locking screw; and
wherein the locking screw is adapted to self-cut into a vertebra and to block the bone screw, the locking screw and the bone screw adapted to anchor the anchoring plate to the vertebra.

23. The implant of claim 22 wherein the locking screw has a head that blocks the bone screw from at least one of a backward displacement and a rotational displacement.

24. The implant of claim 22 wherein the locking screw further comprises a chisel-point end, wherein the chisel point end self-cuts the locking screw into the vertebra.

25. A facet joint implant of claim 1 comprising:
the facet joint spacer adapted to be inserted into a facet joint, the facet joint spacer pivotable between an extended position and a folded position with respect to the anchoring plate, wherein the facet joint spacer is configured such that the facet joint spacer cannot pivot beyond the extended

position.

26. The implant of claim 25 wherein the facet joint spacer includes a rear protrusion to prevent movement of the facet joint spacer beyond the extended position.

5

27. The implant of claim 1 wherein the facet joint spacer includes a convex top surface and a bottom surface, wherein the top surface tapers toward the bottom surface at an angle to form a front edge.

10 28. The facet joint implant of claim 1, wherein the anchoring plate includes an engagement aperture adapted to receive a retractable engaging member of an implanting tool.

29. The implant of claim 1 wherein the anchoring plate further comprises a side surface having an protrusion adapted to correspondingly register in a receiving slot in an implanting tool.

15

30. The implant of claim 1 wherein the anchoring plate further comprises a pair of winged protrusions along opposing side surfaces, wherein the protrusions are adapted to register in corresponding slots in an implanting tool.

20 31. The facet joint implant of claim 1, in combination with a tool for sizing a facet joint in order to select a facet joint implant for implanting in the facet joint, said tool comprising:

a handle;

an inter-facet sizer, the inter-facet sizer having a rounded distal end and a proximal end and connected with the handle at the proximal end; and

25 a stop at the proximal end of the inter-facet sizer, the stop adapted to prevent over-insertion of the inter-facet sizer during sizing.

32. The tool as in claim 31 wherein the distal end of the inter-facet sizer is tapered in thickness to facilitate insertion into the cervical facet joint to be sized.

30

33. The facet joint implant of claim 31 wherein the articulation joint is narrower than the facet joint spacer.

34. The implant of claim 1 wherein the facet joint spacer and the flexible connection together are

formed into a P-shape.

35. The facet joint implant of claim 1 in combination with a distraction tool to distract adjacent facets in a spine for insertion of the implant comprising:

5 a. a distraction head having a first head component and a second head component coplanar with one another in a closed position; and

b. an actuatable handle coupled to the distraction head, wherein the first head component and the second head component are non-coplanar when the handle is operated to actuate the first and second head components to an open position.

10

36. The tool of claim 35 wherein the first head component includes a first set of fingers and the second head component includes a second set of fingers, wherein the first and second sets of fingers are alternately configured with one another.

15

37. The facet joint implant of claim 1 in combination with an implanting tool to insert implant, the tool comprising:

a. a handle having a switch; and

b. an engaging head extending from the handle and adapted to receive the implant, the engaging head including a forked end having a pair of sidewalls adapted to receive corresponding sidewalls of the implant, the engaging head coupled to the actuating switch and configured to allow the received implant to be disengaged therefrom when the switch is actuated.

20

38. The tool of claim 37 wherein the engaging head further comprises an engaging member positioned between the sidewalls and movable between an extended position and a retracted position when the switch is actuated, the engaging member adapted to be inserted into an engaging aperture of the implant when in the extended position.

25

39. The tool of claim 37 wherein at least one of the sidewalls of the engaging head includes a slot adapted to receive a protrusion from the sidewall of the implant.

30

40. The facet joint implant of claim 1 including:

a bone screw that is disposed through the anchoring plate and is adapted to secure the anchoring plate to the vertebra;

a locking screw that holds the bone screw in place in the anchoring plate;

wherein said locking screw has a first position that locks the bone screw in the anchoring plate and a second position that allows the bone screw to be removed from the anchoring plate.

41. The implant of claim 40 wherein said locking screw has an asymmetrical head.

5

42. The implant of claim 41 wherein said head includes a cut-out that allows the bone screw to be removed from the anchoring plate.

10

43. The implant of claim 40 wherein said locking screw includes a head with a concave portion and a convex portion.

44. The implant of claim 40 wherein the bone screw is received in a recess in the anchoring plate and the locking screw is received in a recess of the anchoring plate.

15

45. The facet joint implant of claim 1 including at least one protrusion extending from the facet joint spacer which is adapted to retain the facet joint spacer in the facet joint.

46. The implant of claim 45 wherein:

said facet joint spacer has a superior surface and an inferior surface;

20

the superior surface is adapted to be positioned adjacent to an inferior facet of a facet joint;

the inferior surface is adapted to be positioned adjacent to a superior facet of a facet joint; and

the at least one protrusion extends from the inferior surface and is adapted to engage the superior facet.

25

47. The implant of claim 45 wherein:

a plurality of protrusions extend from the inferior surface.

48. The implant of claim 45 wherein:

the at least one protrusion points away from a direction of insertion of the facet joint spacer

30

into a facet joint.

49. The facet joint implant of claim 1 wherein:

said facet joint spacer including an inferior shim and a superior shim, wherein said inferior shim is stiffer and less compliant than the superior shim.

50. The implant of claim 49 wherein said superior shim is molded onto said inferior shim.

51. The implant of claim 49 wherein said inferior shim is comprised of a metal and said superior
5 shim is comprised of a polymer.

52. The implant of claim 49 wherein said inferior shim consists of one of titanium and stainless
steel and the superior shim consists of polyaryletherketone.

10 53. The facet joint implant of claim 49 wherein said inferior shim is comprised of a different
material than the superior shim.

54. The implant of claim 42 wherein said cut-out is crescent shaped.

15

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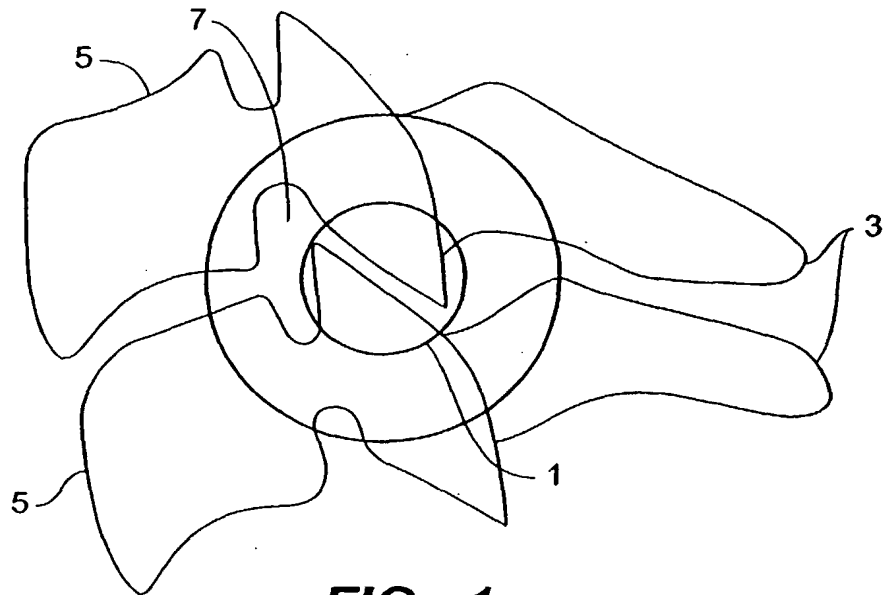


FIG. 1

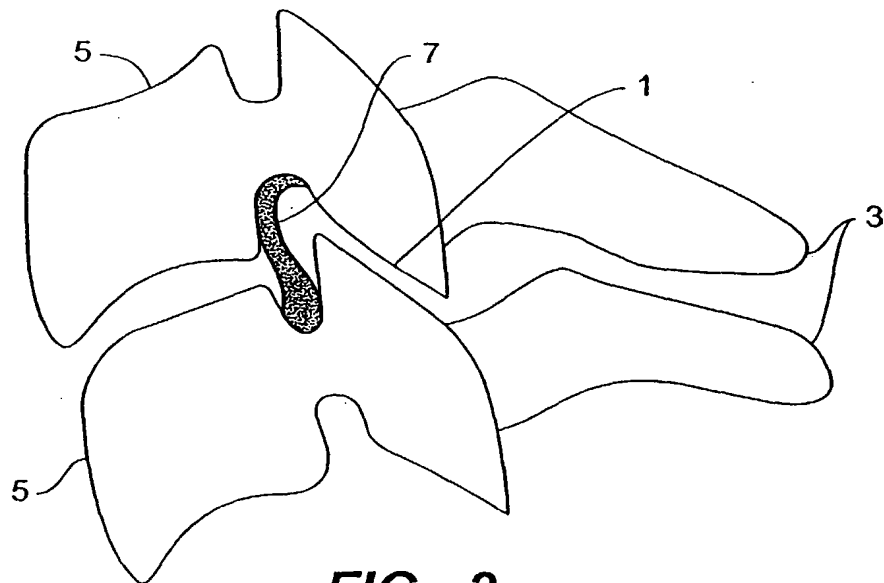


FIG. 2

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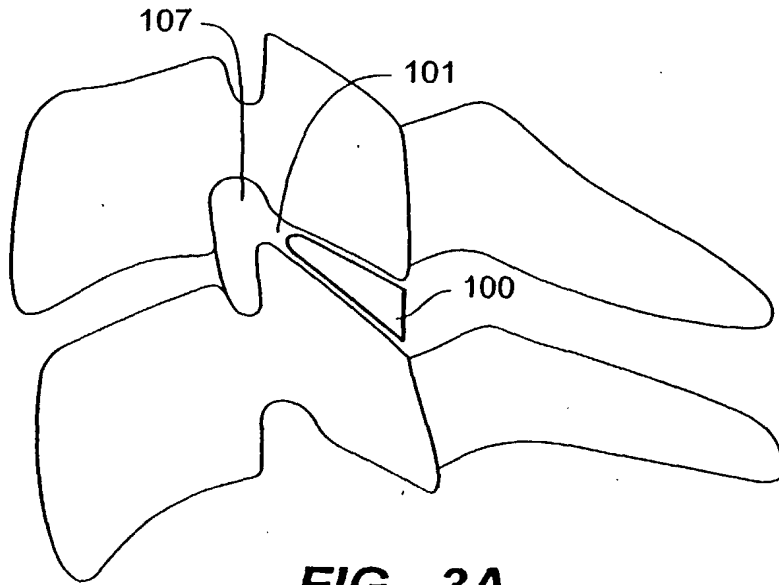


FIG. 3A

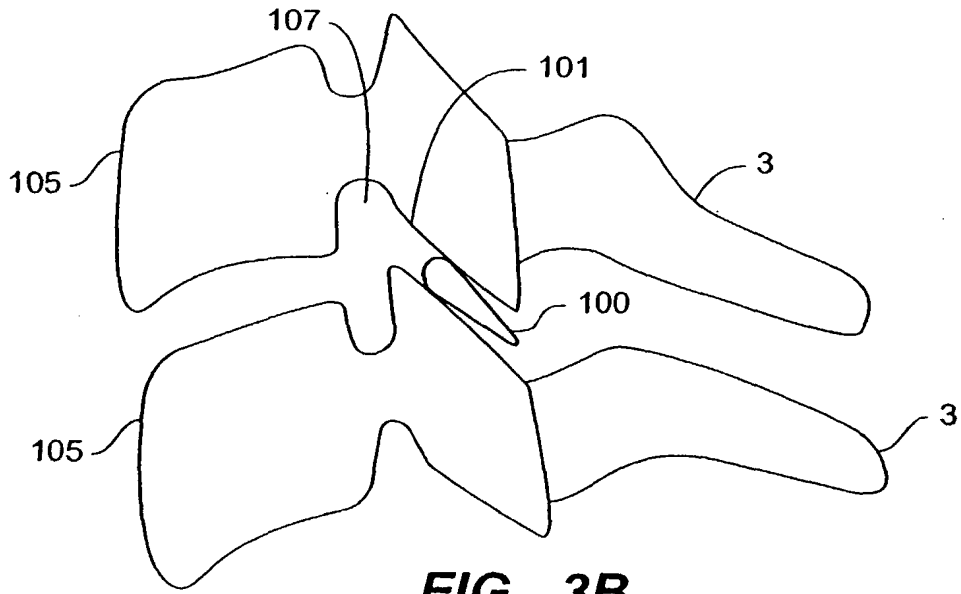


FIG. 3B

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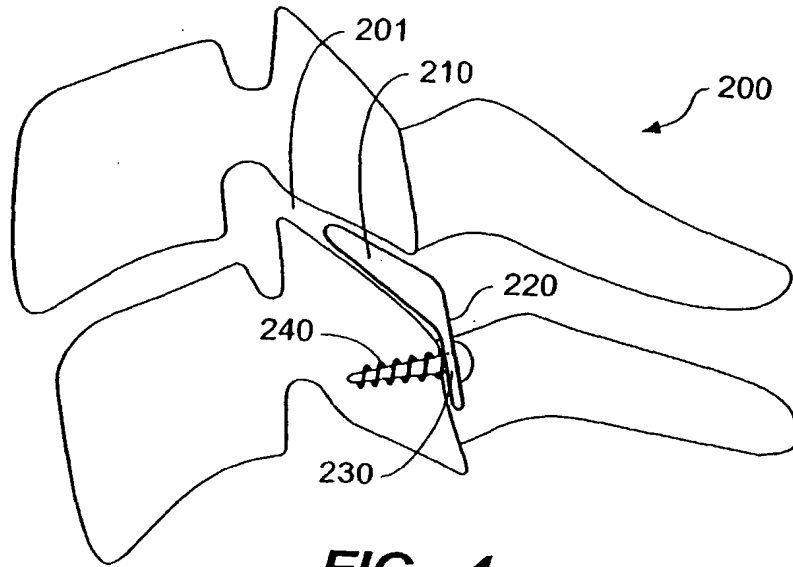


FIG. 4

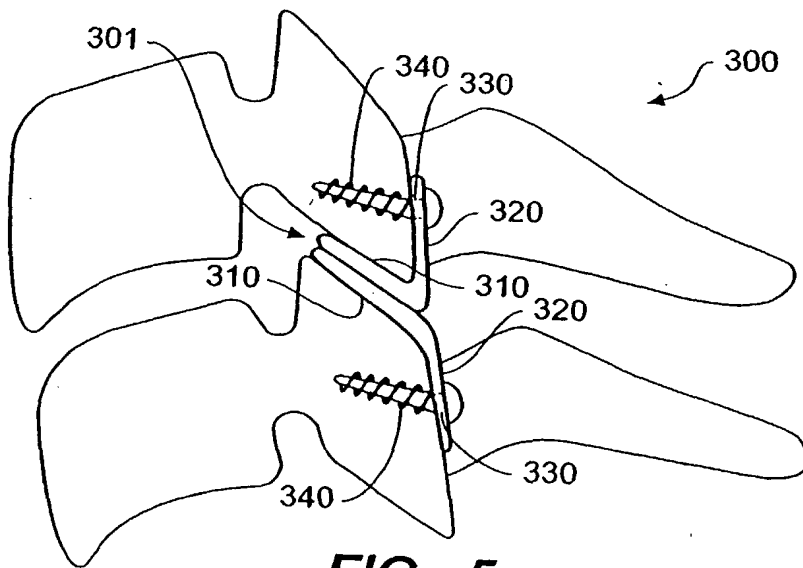


FIG. 5

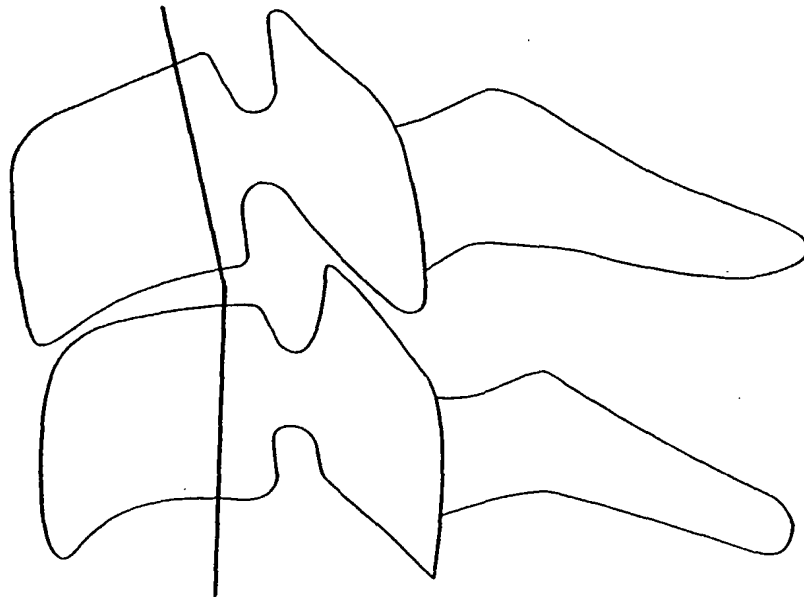


FIG. 6

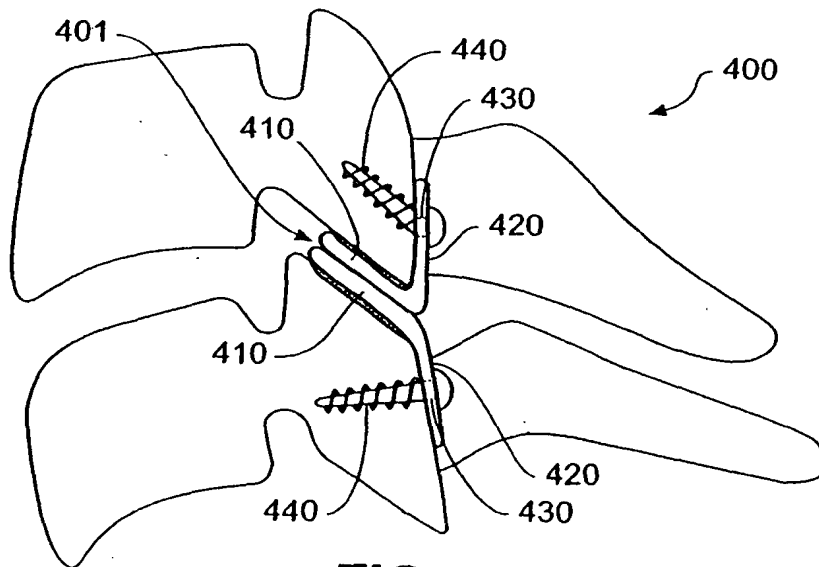


FIG. 7

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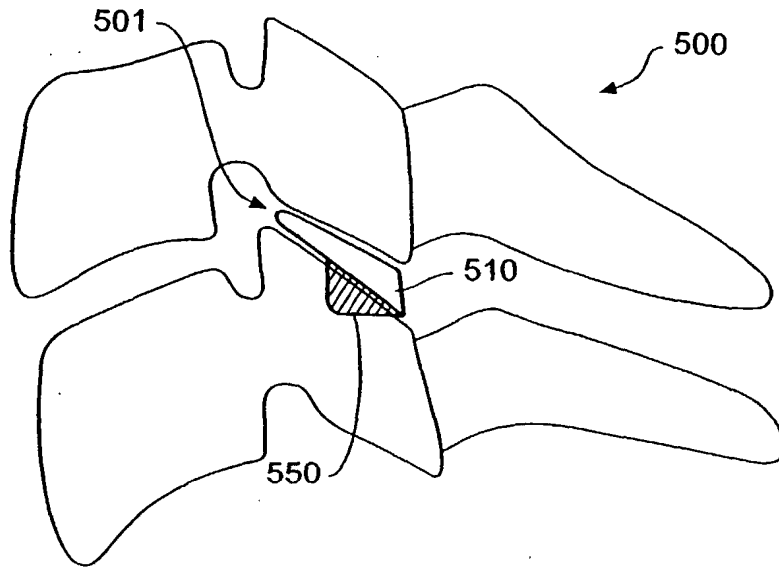


FIG. 8

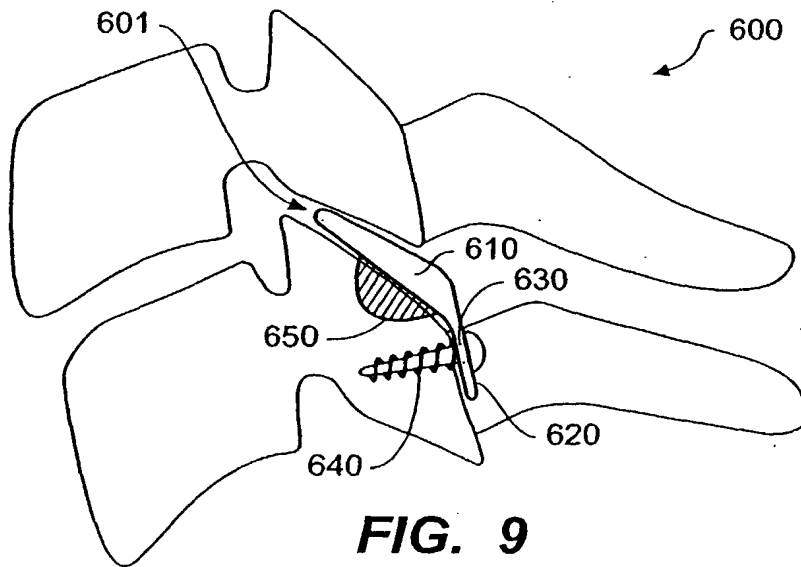


FIG. 9

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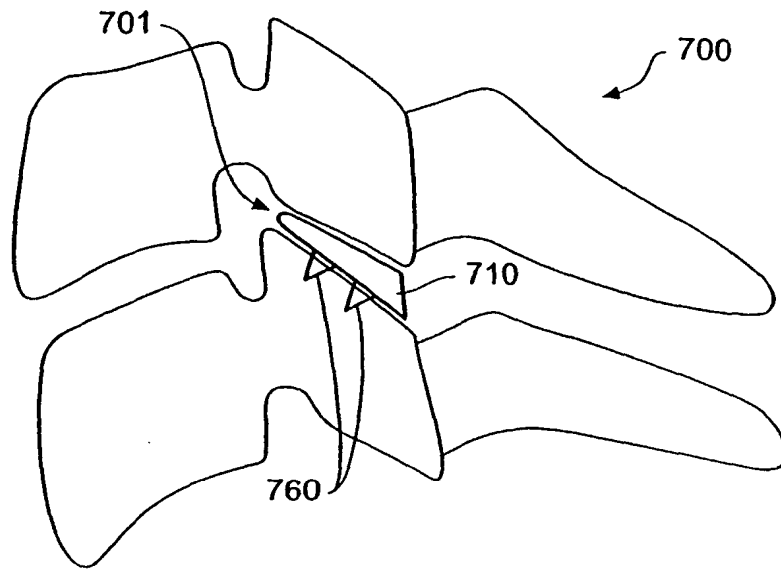


FIG. 10

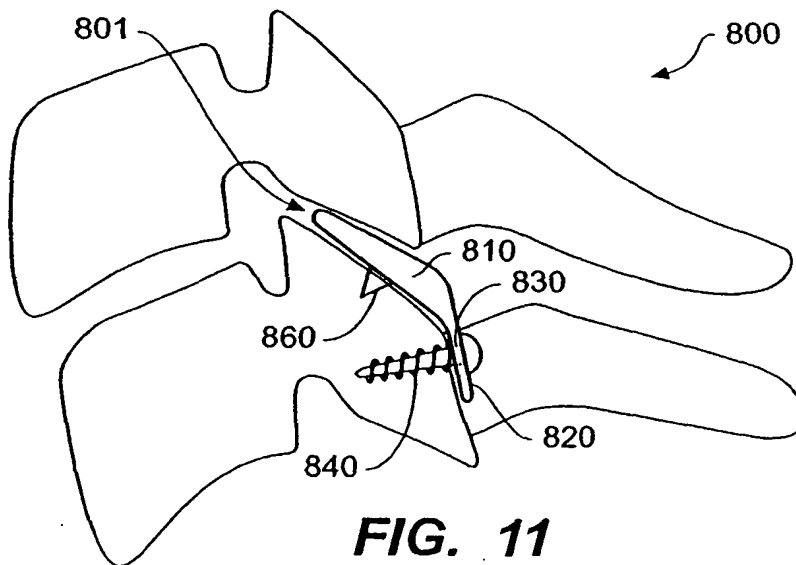


FIG. 11

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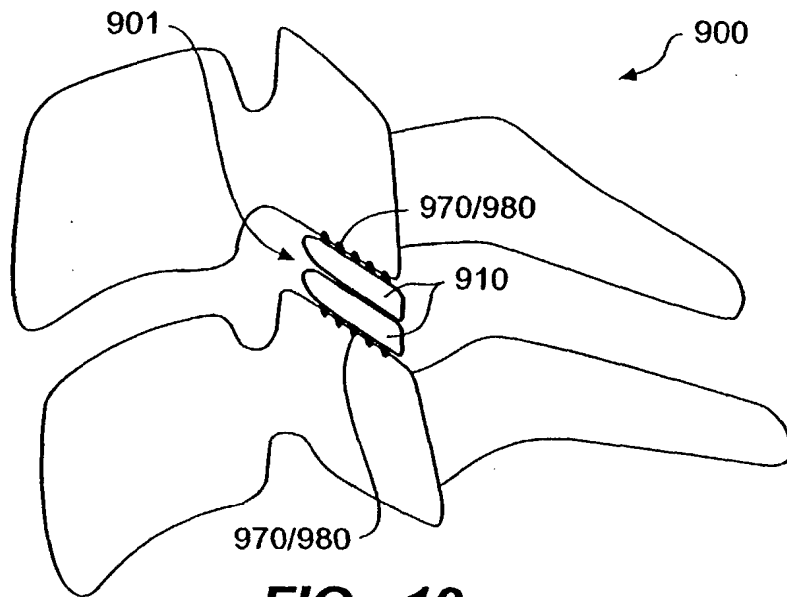


FIG. 12

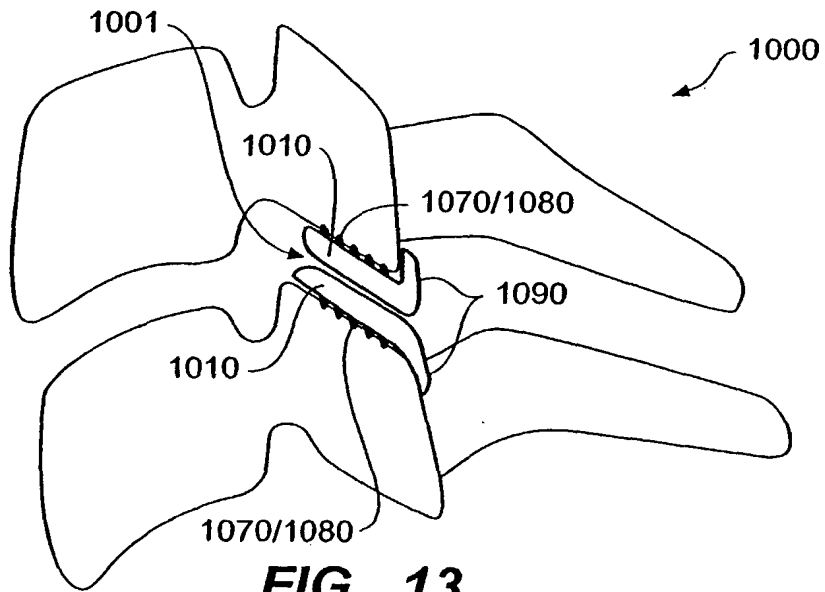
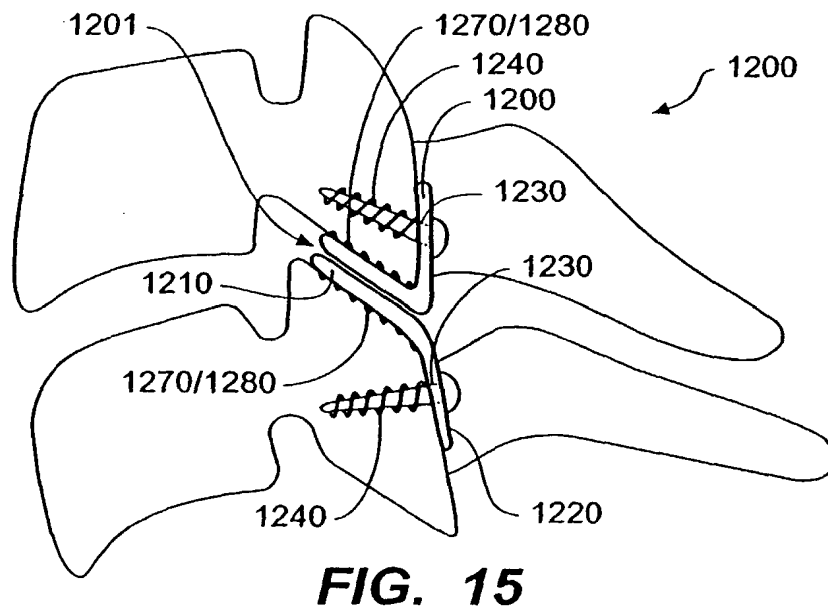
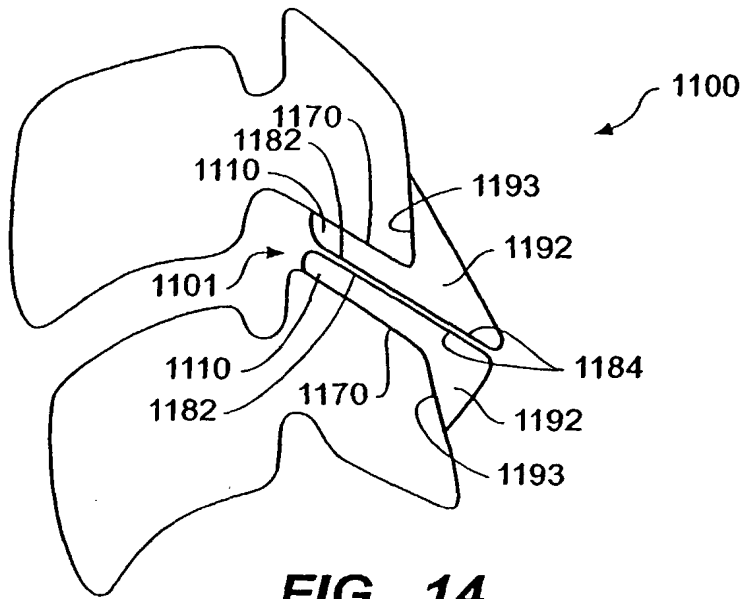
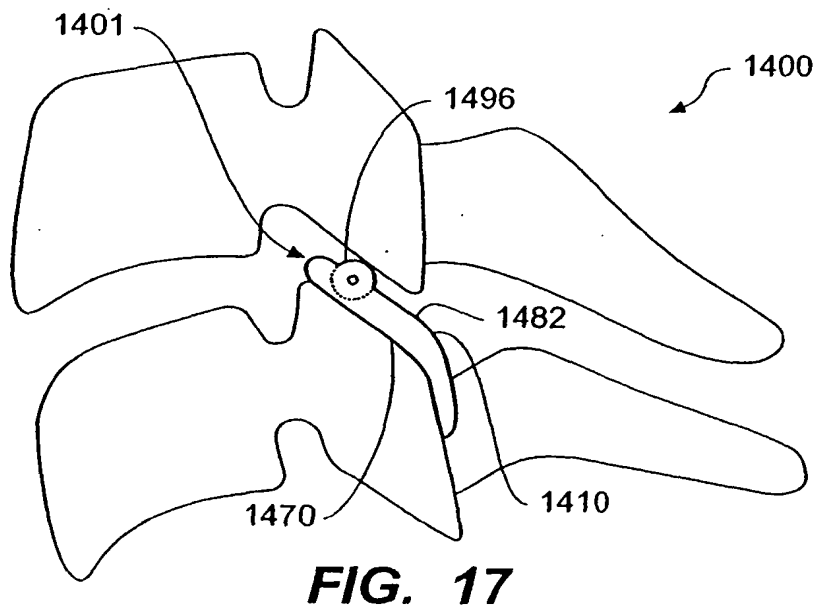
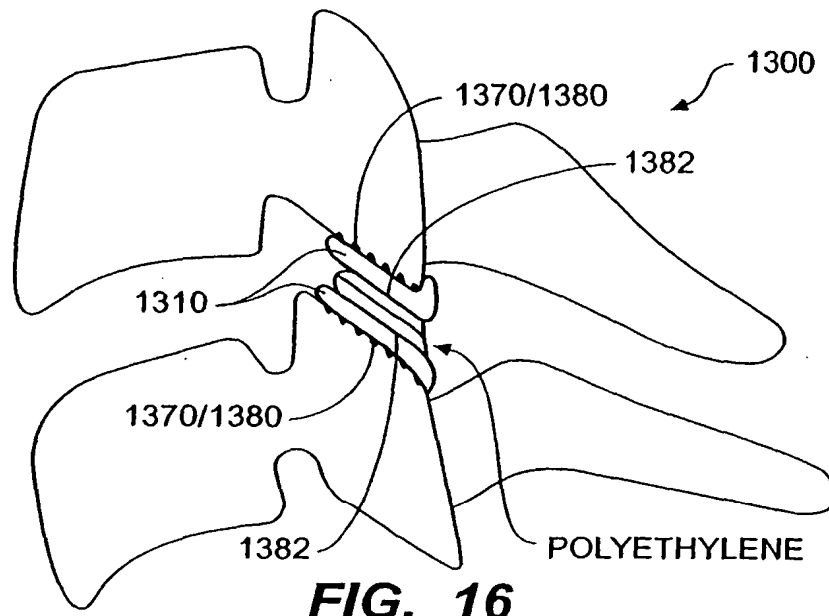


FIG. 13

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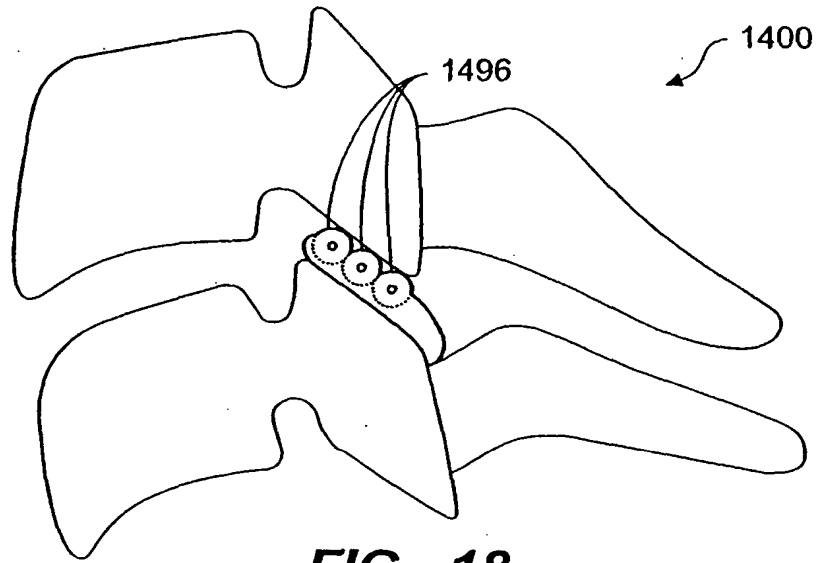


FIG. 18

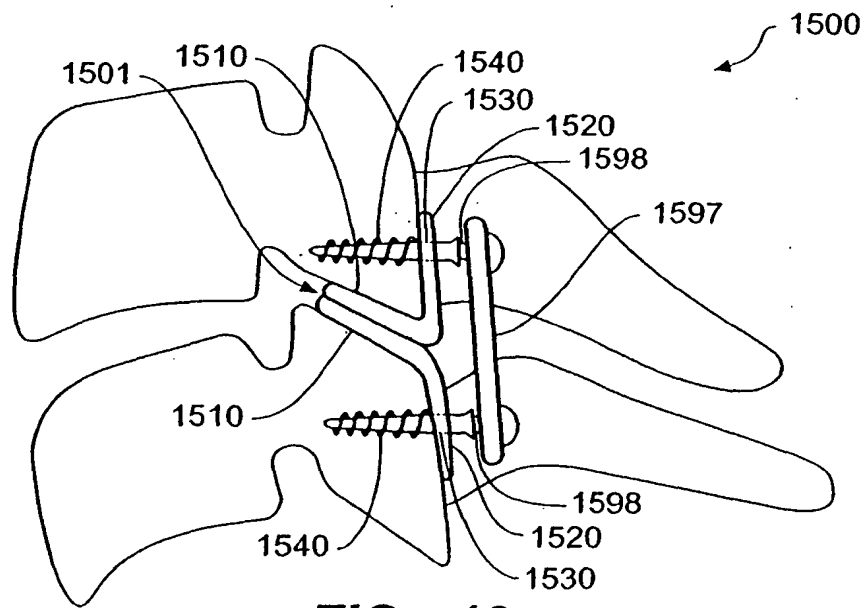


FIG. 19

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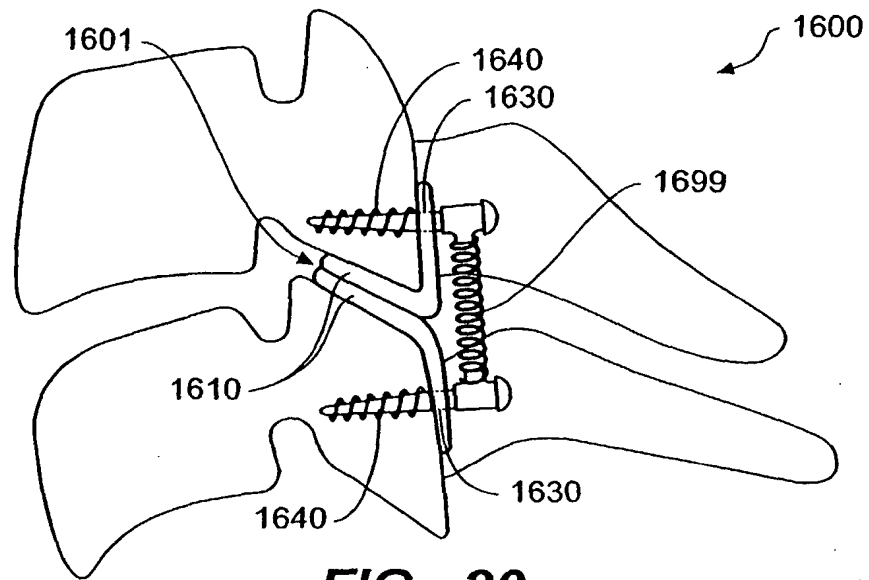


FIG. 20

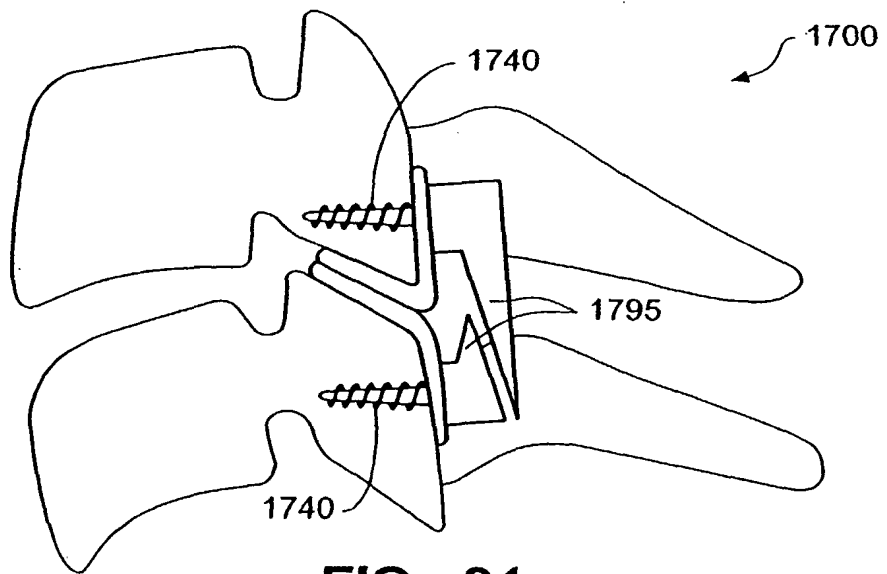


FIG. 21

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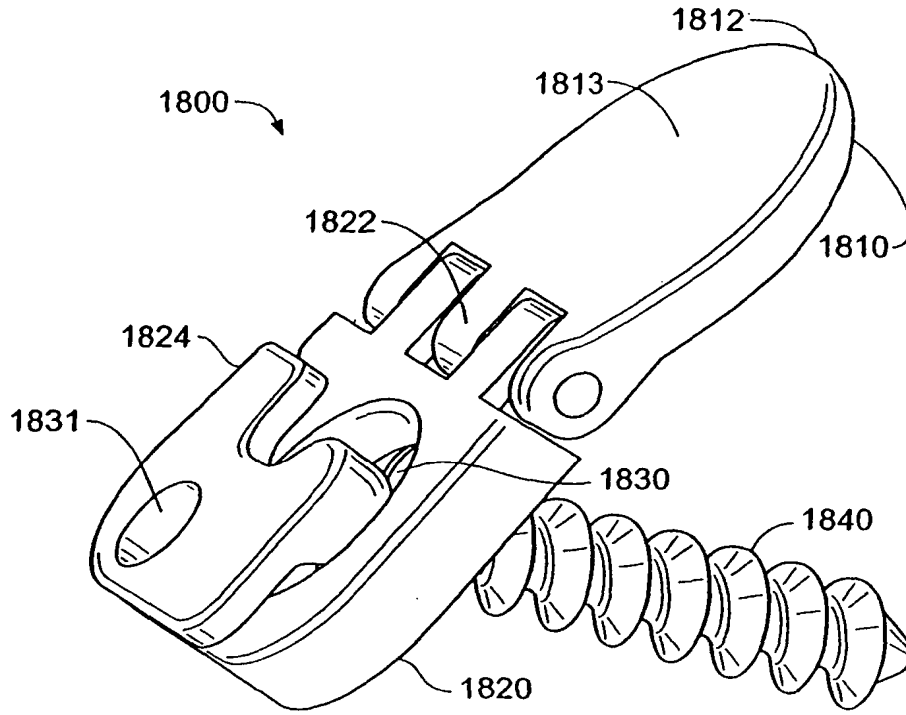


FIG. 22A

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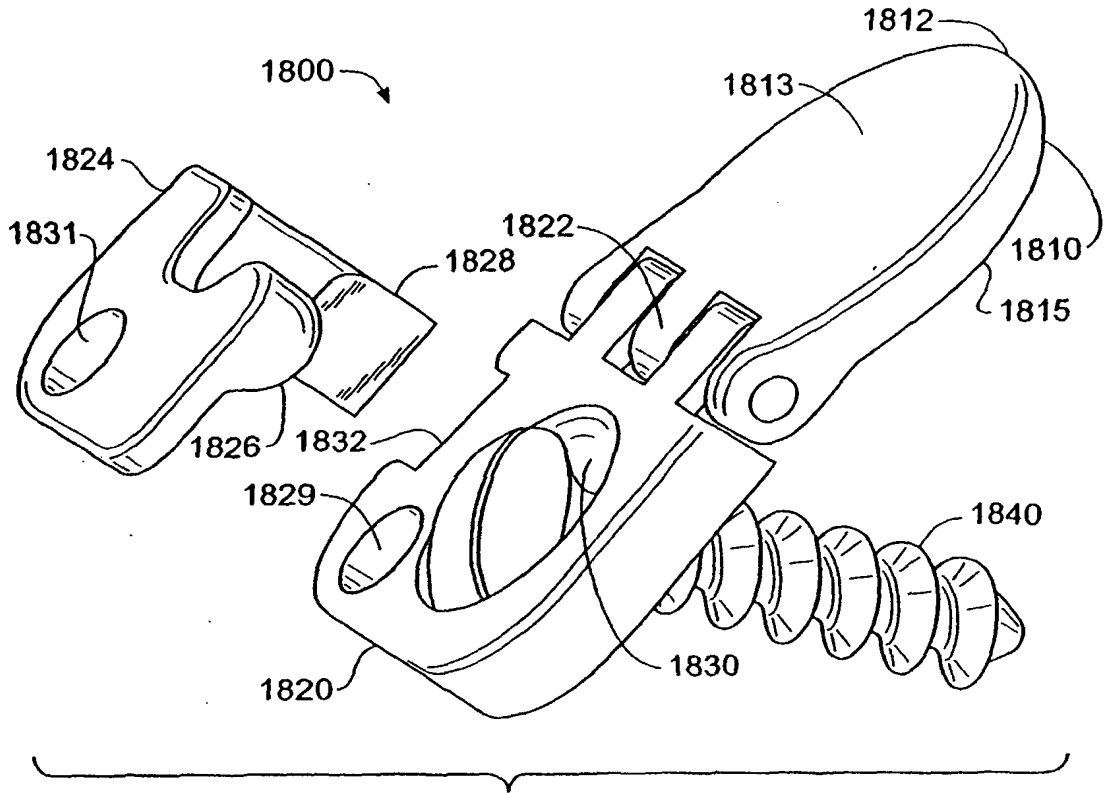


FIG. 22B

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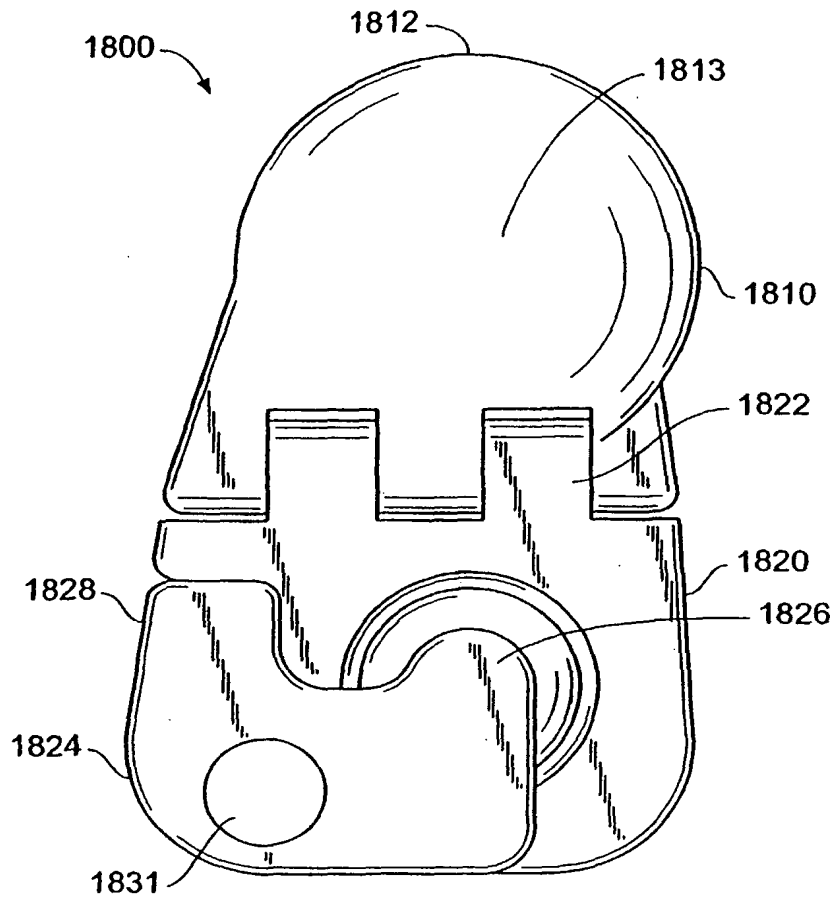


FIG. 23A

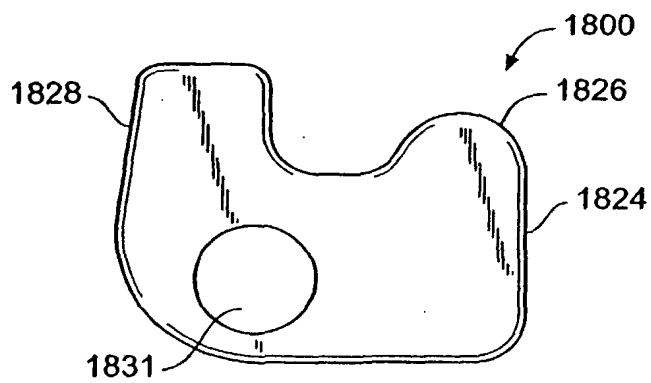


FIG. 23B

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FIG. 24A

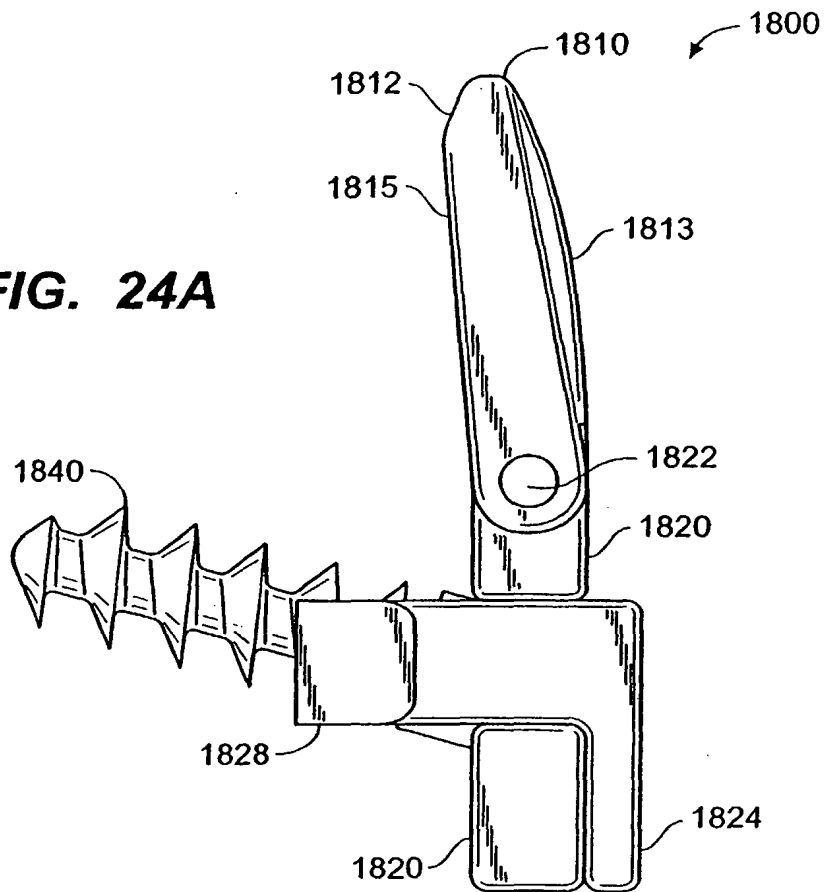
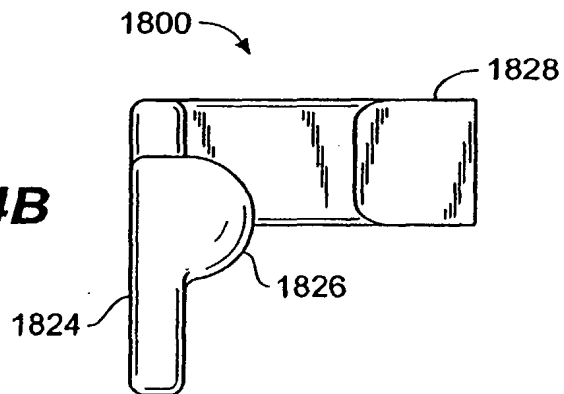


FIG. 24B



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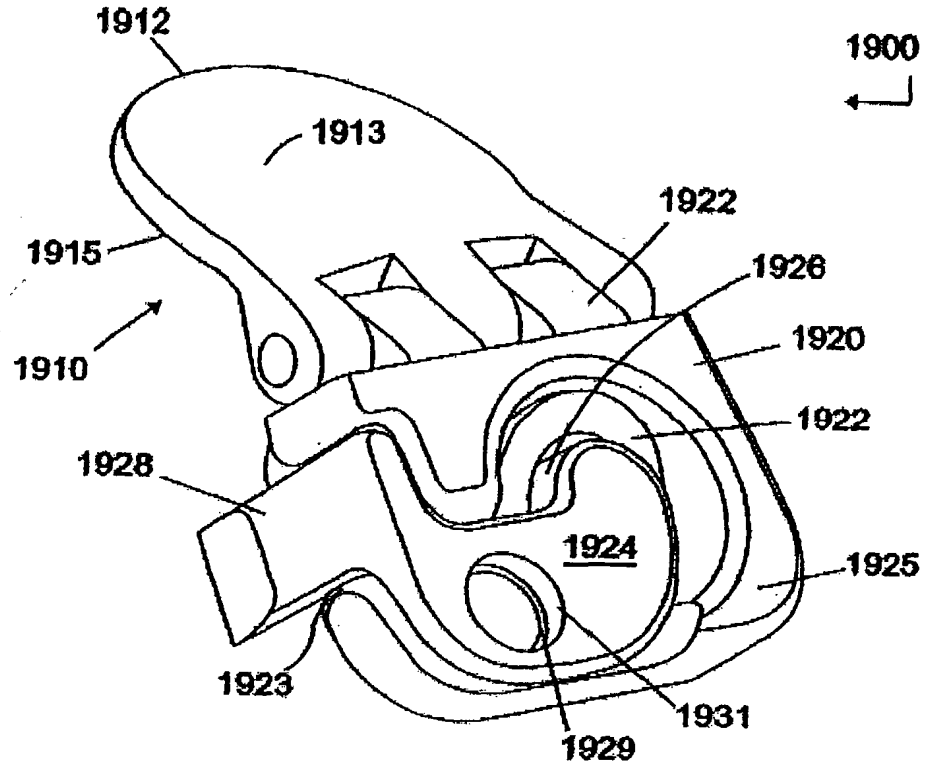


FIG. 25A

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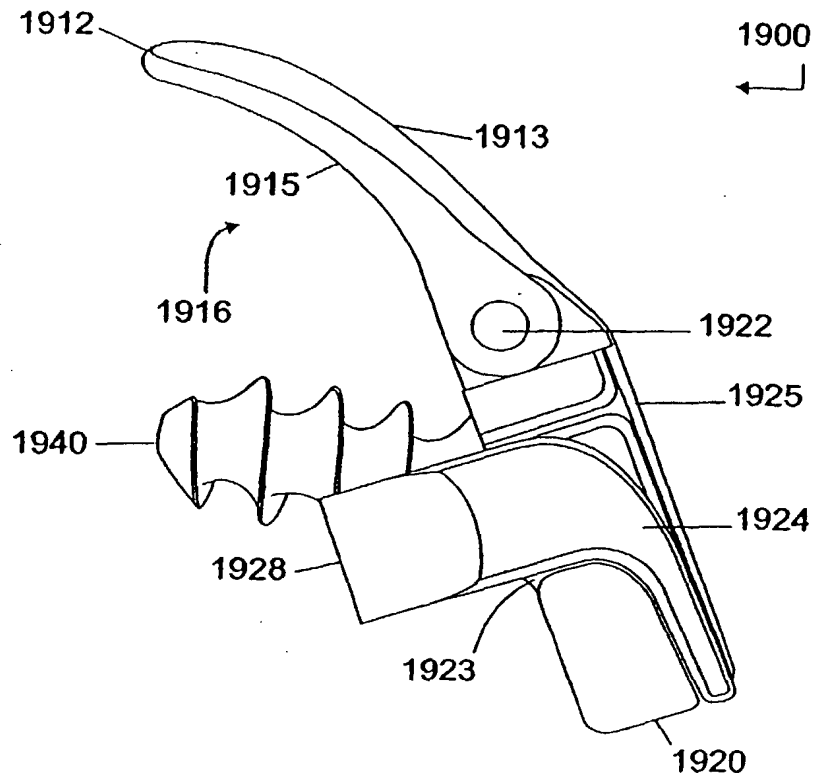
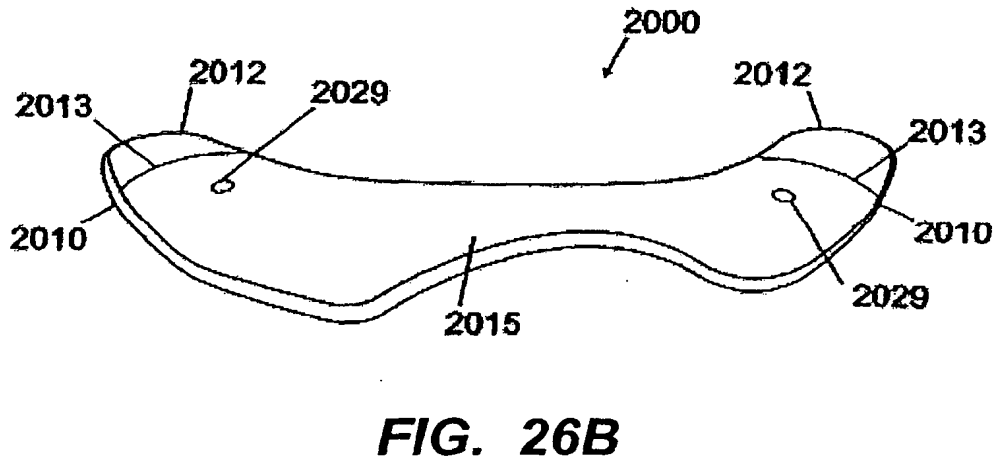
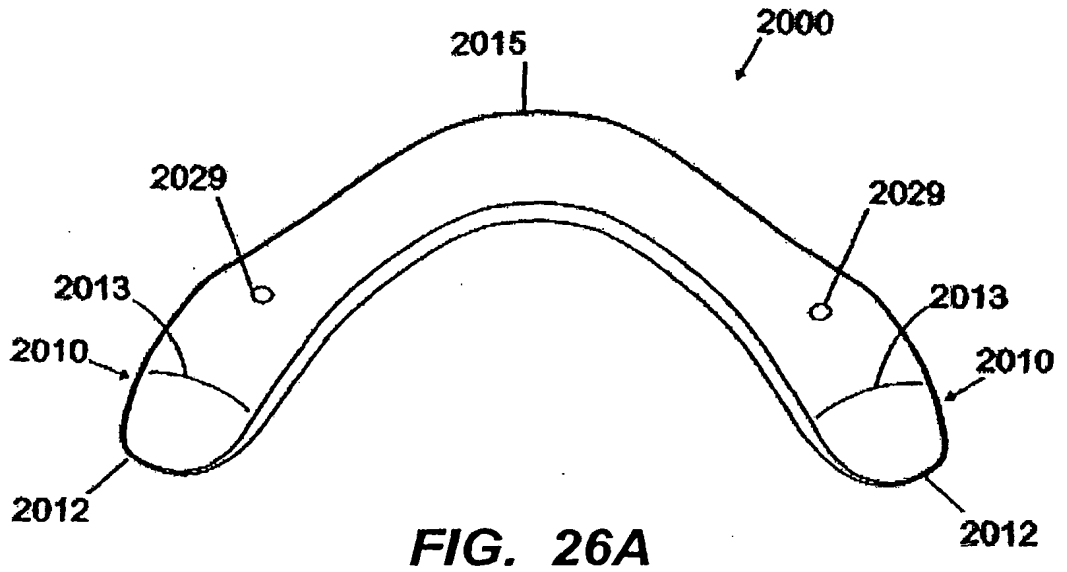


FIG. 25B



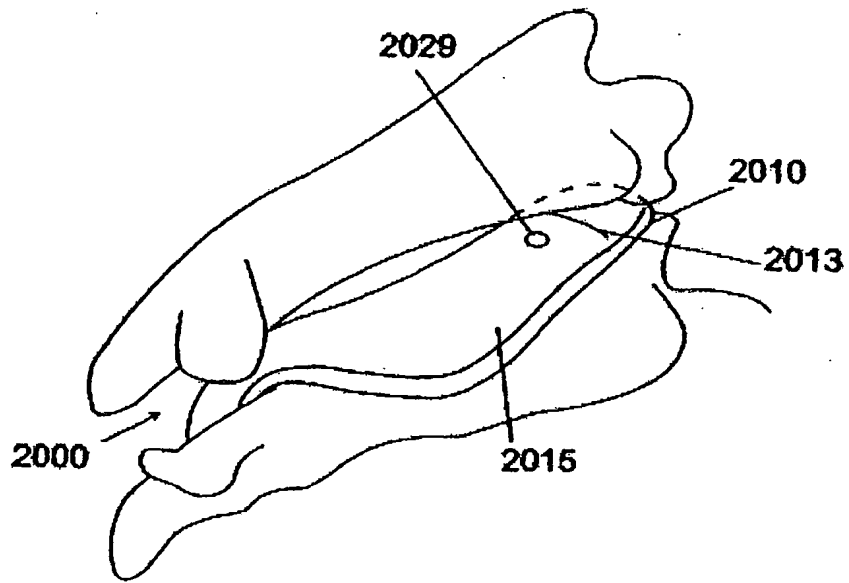


FIG. 27A

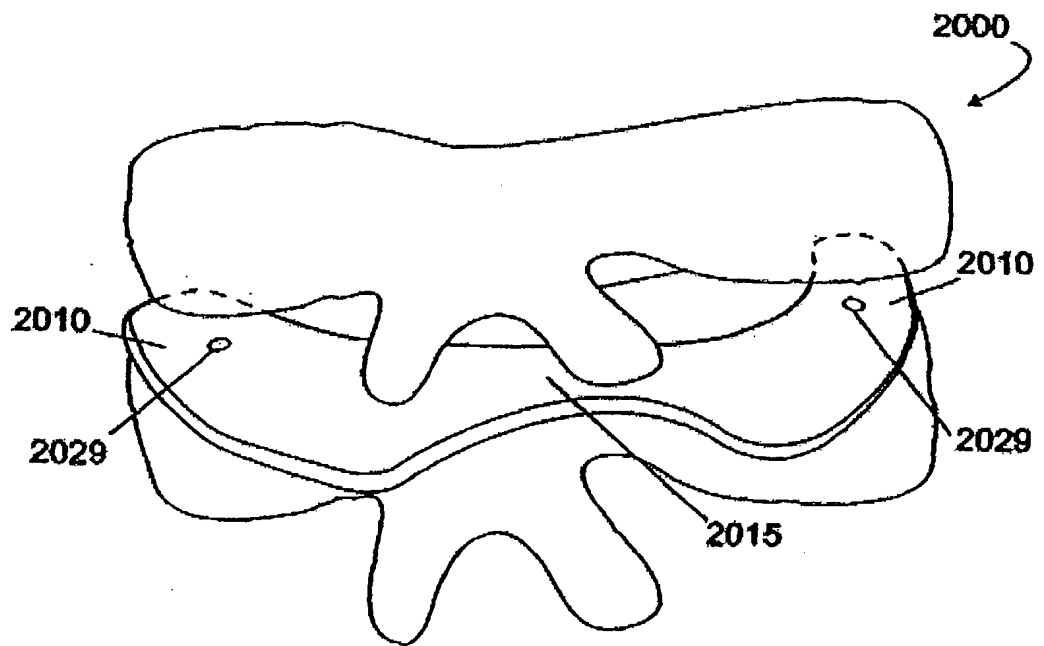


FIG. 27B

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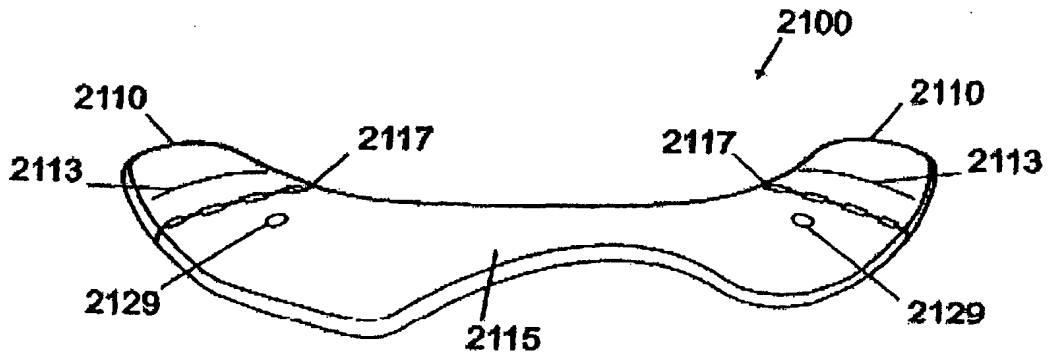


FIG. 28A

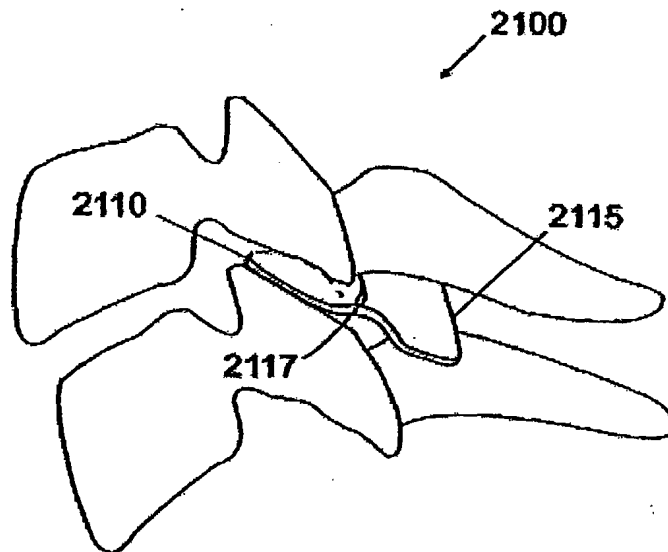
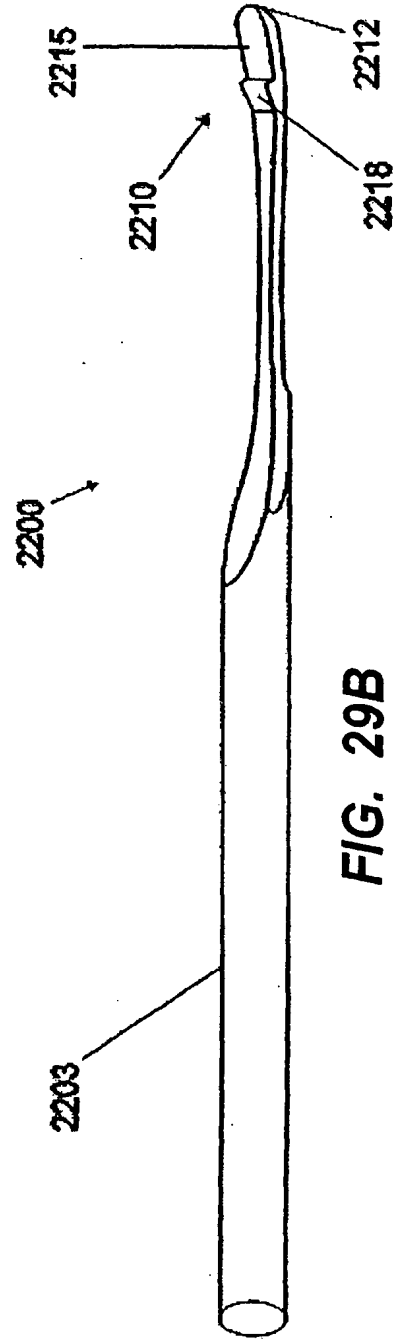
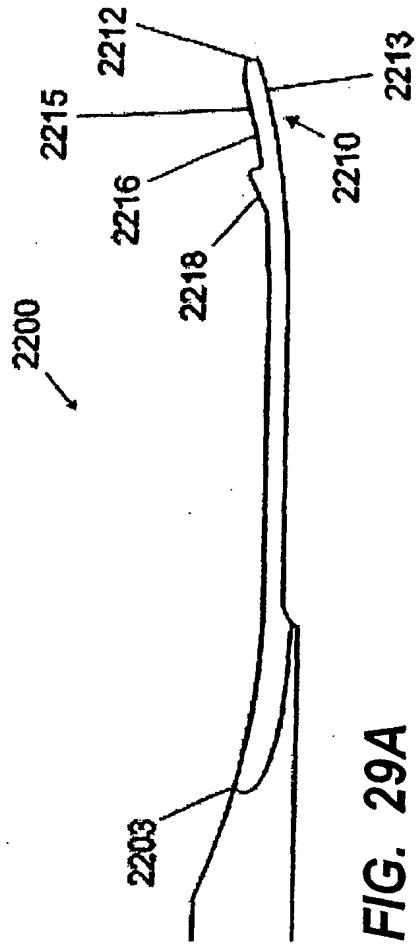


FIG. 28B



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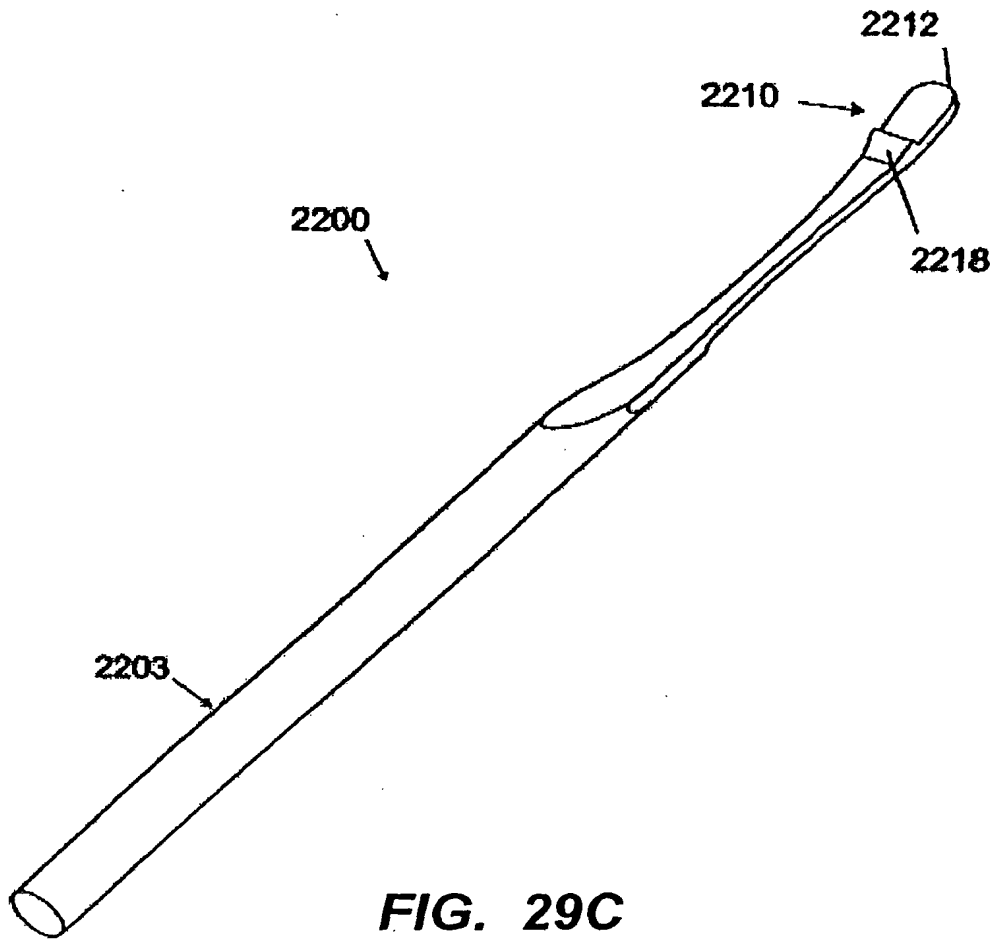


FIG. 29C

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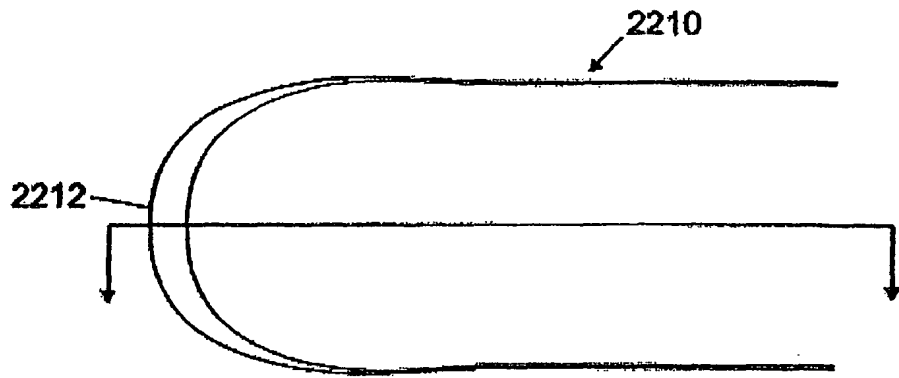


FIG. 29D

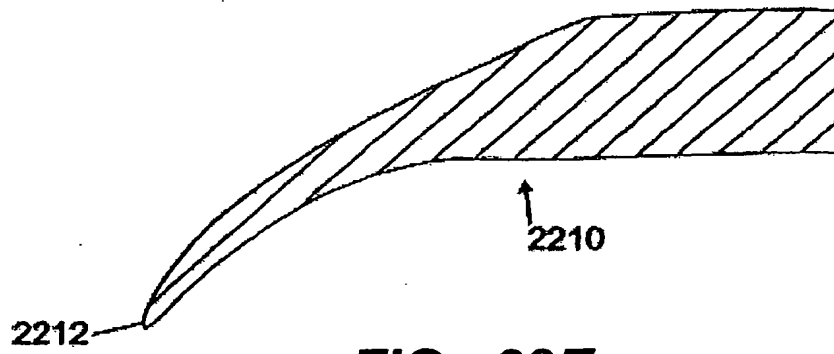


FIG. 29E

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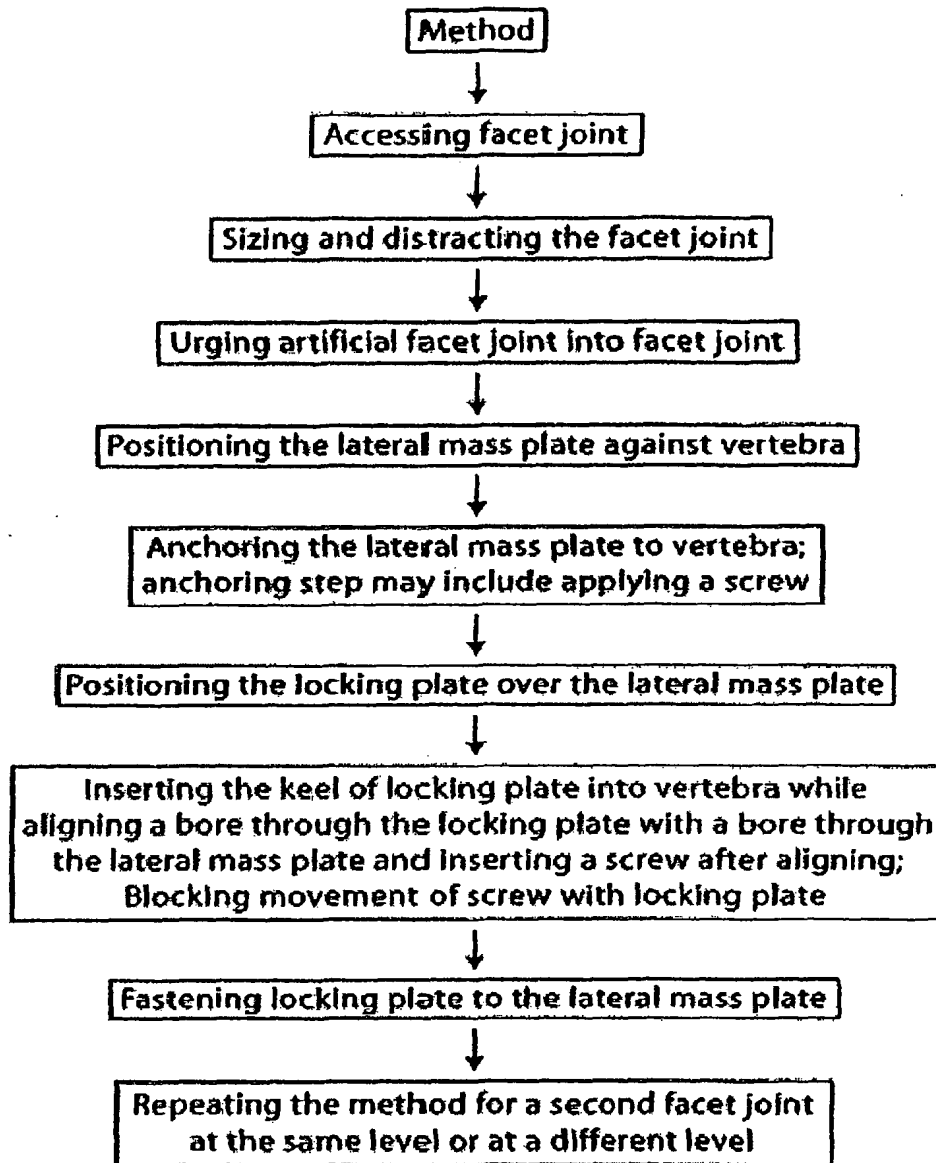


FIG. 30

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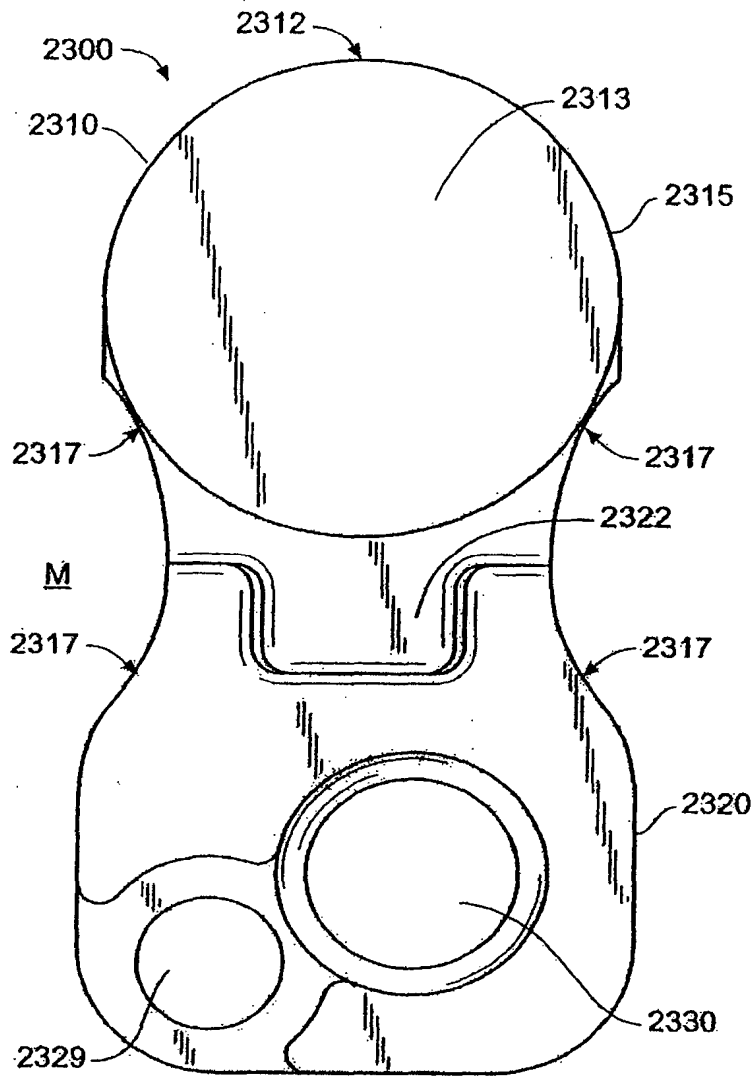


FIG. 31A

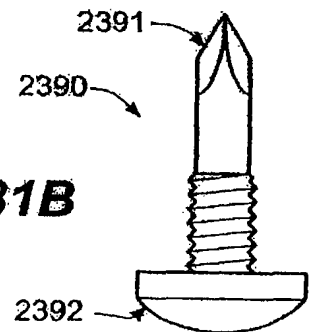


FIG. 31B

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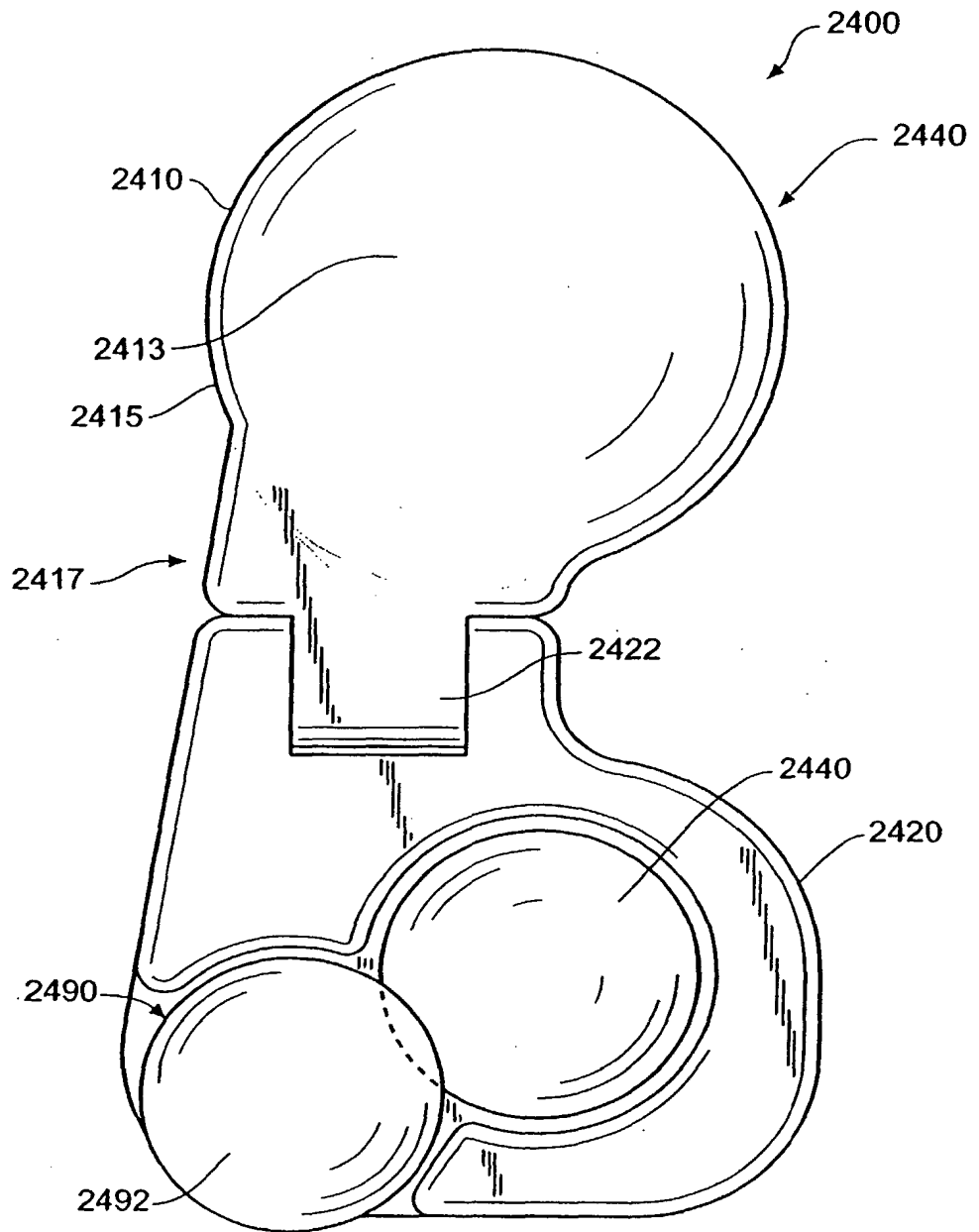
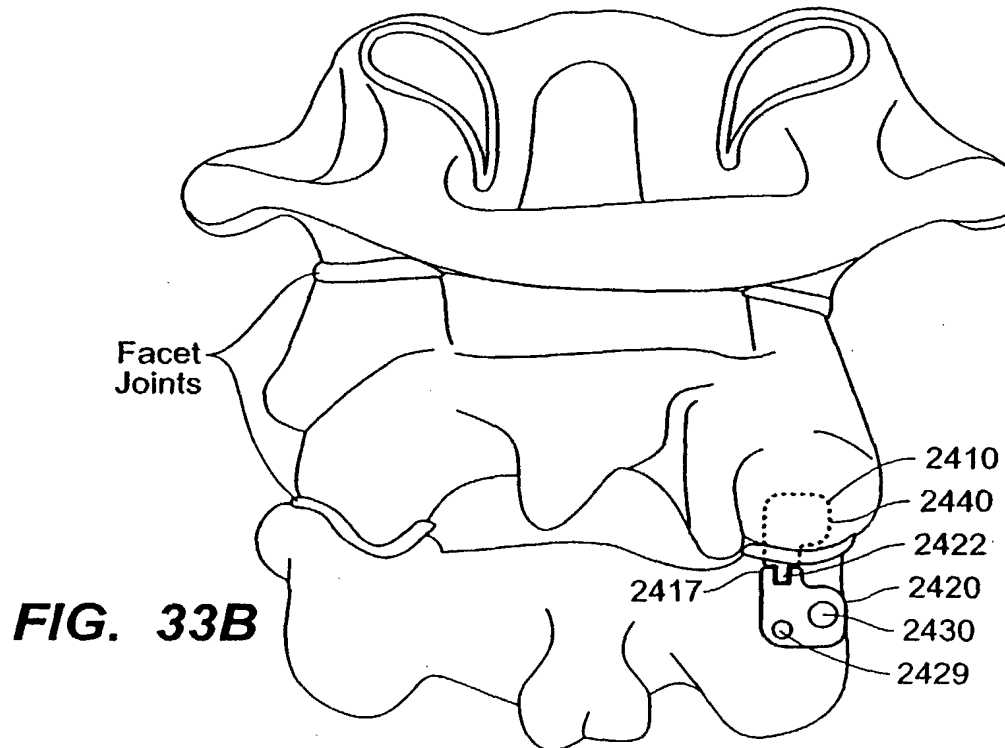
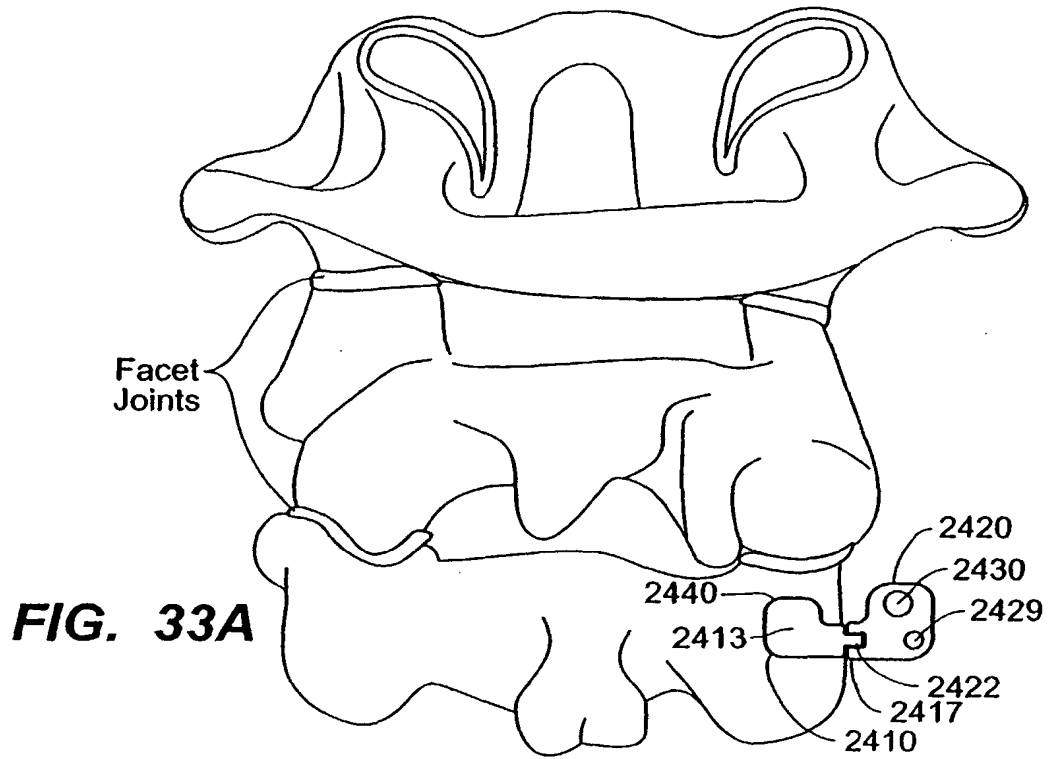


FIG. 32

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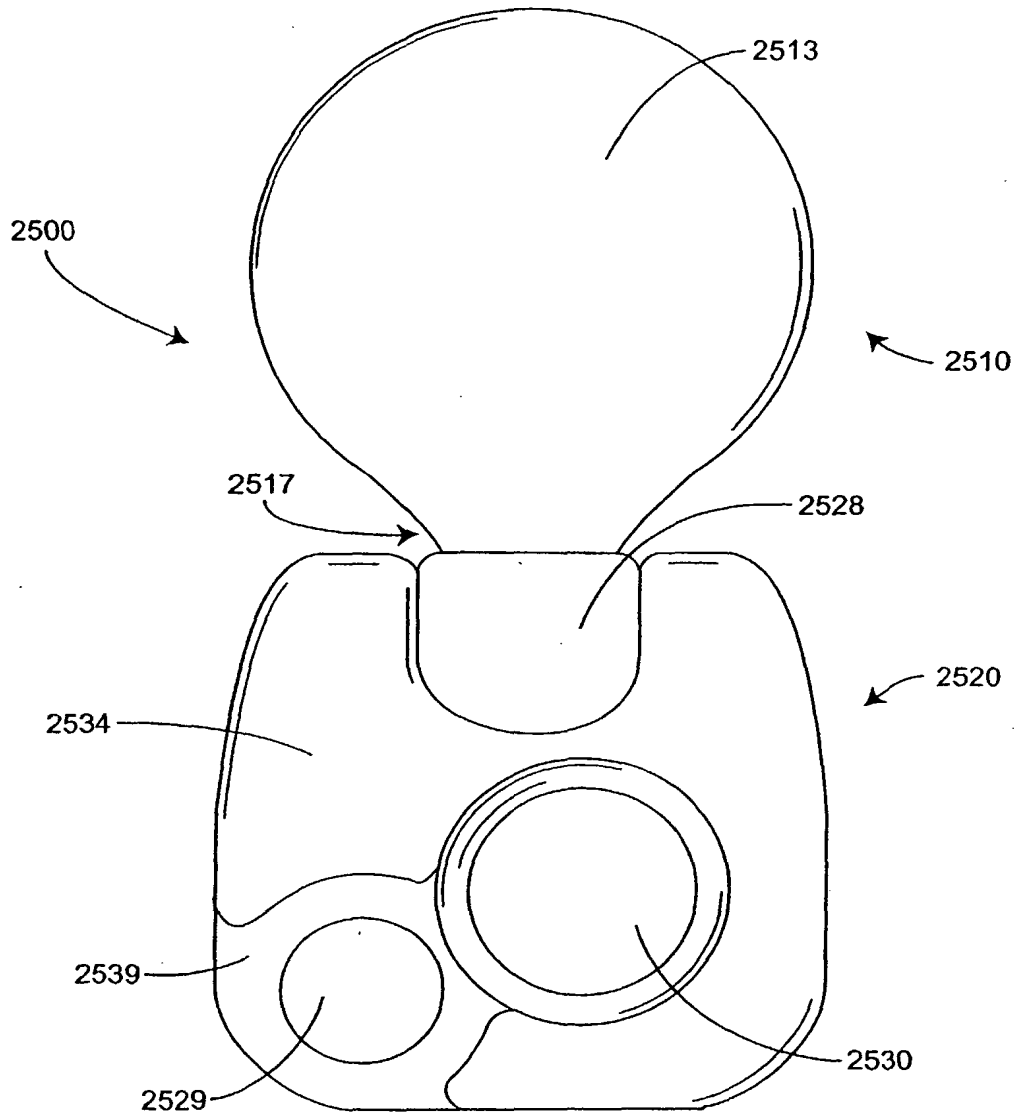


FIG. 34A

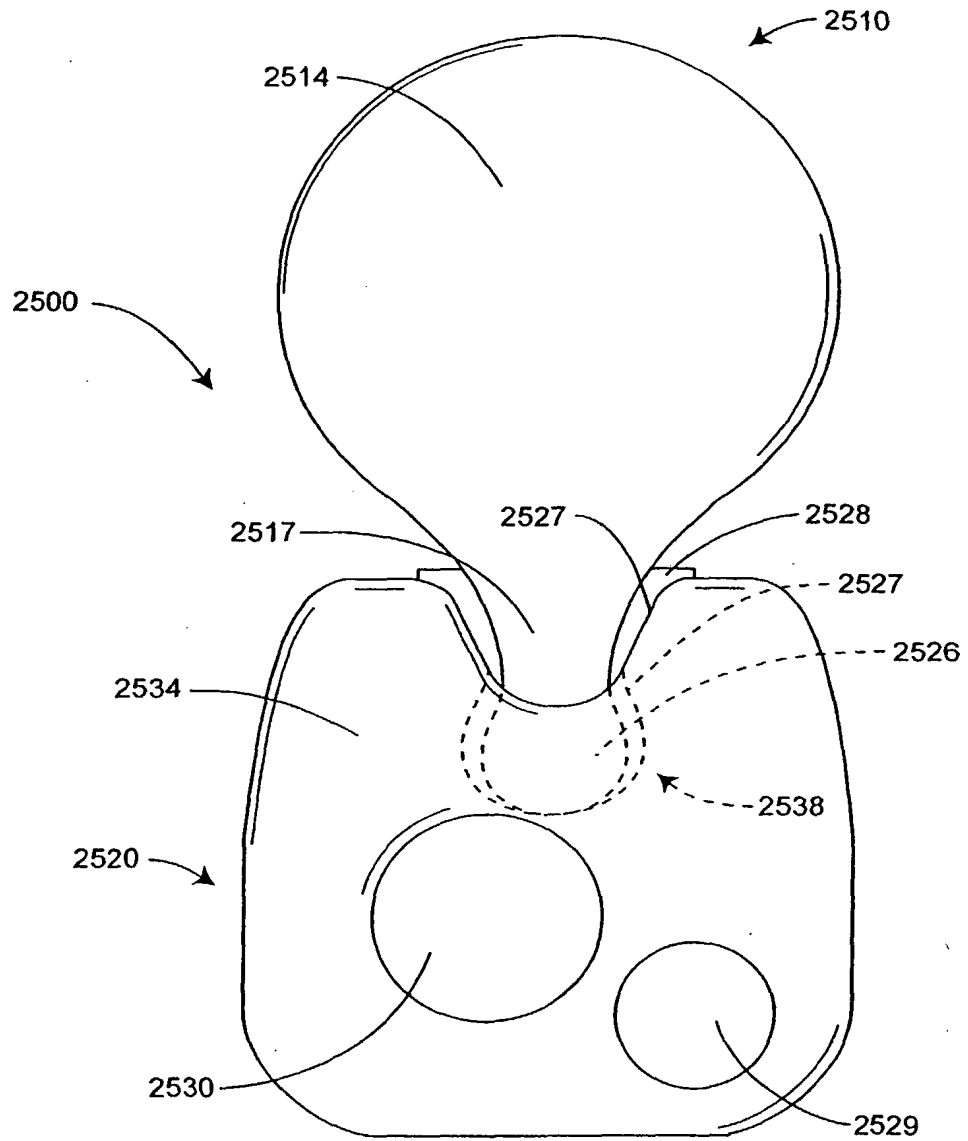


FIG. 34B

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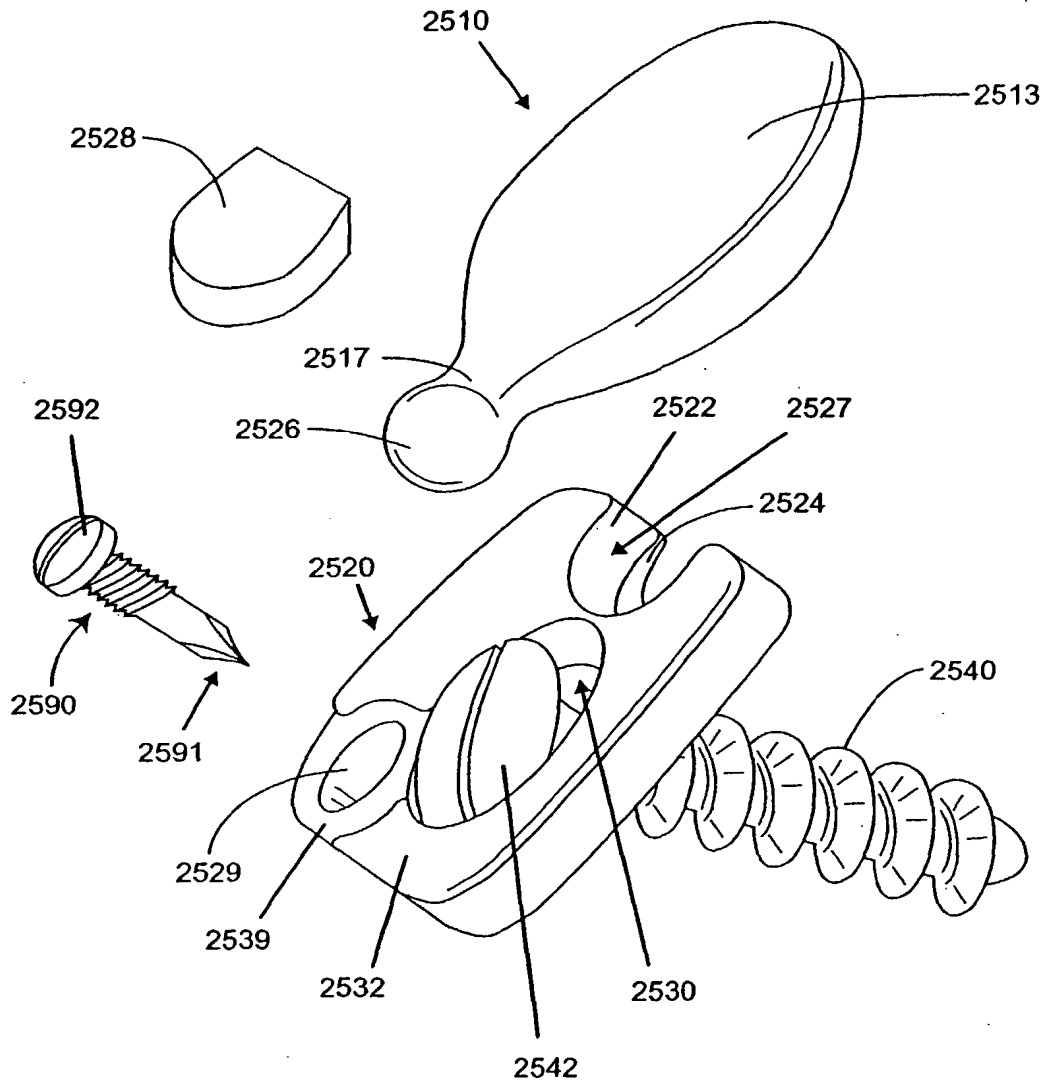


FIG. 35

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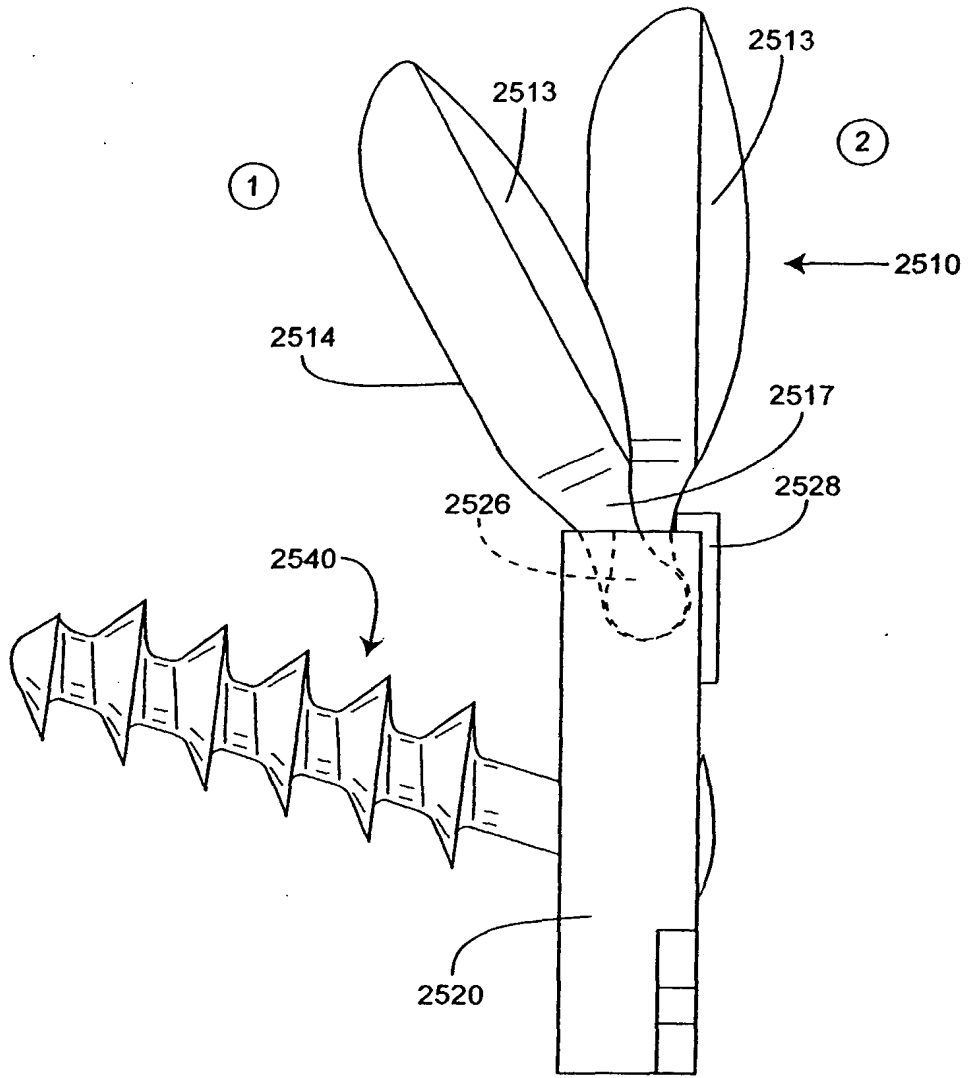


FIG. 36A

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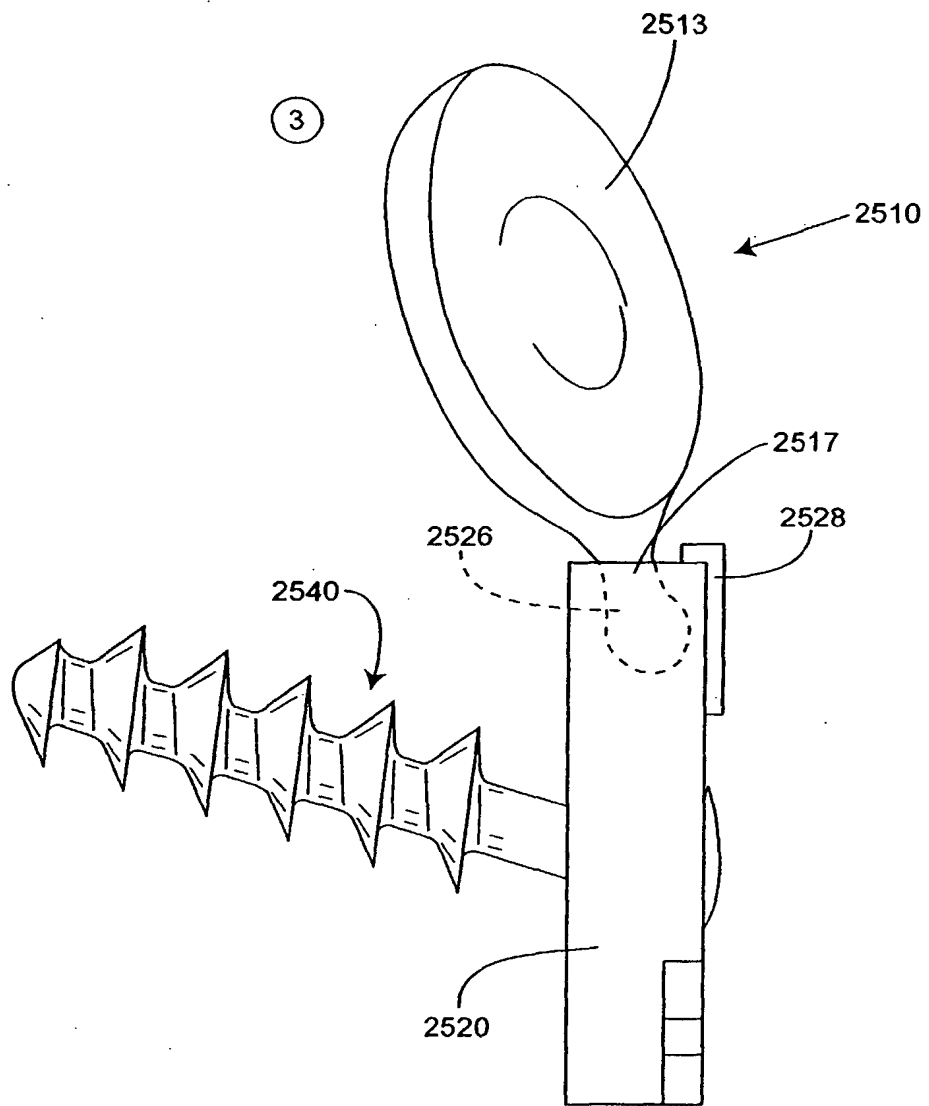


FIG. 36B

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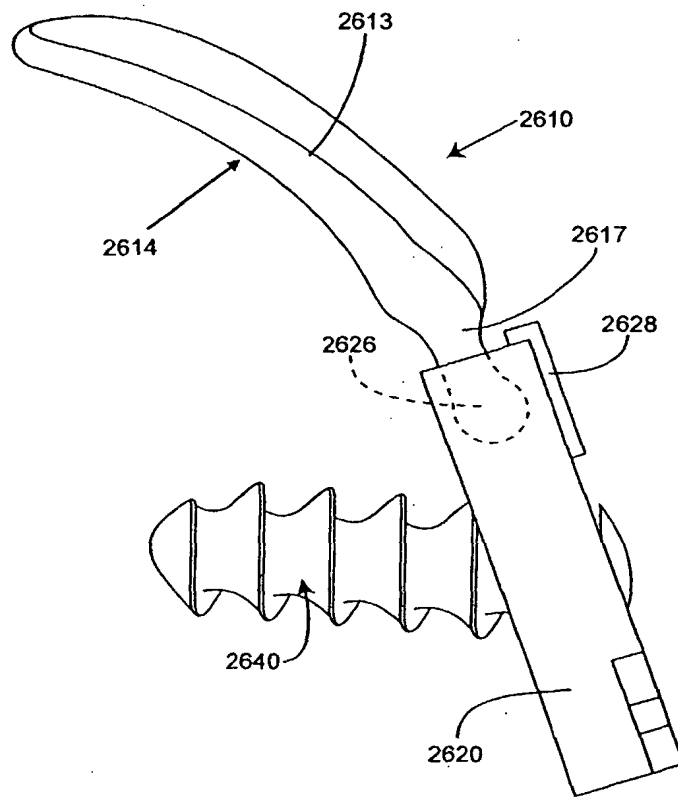


FIG. 37

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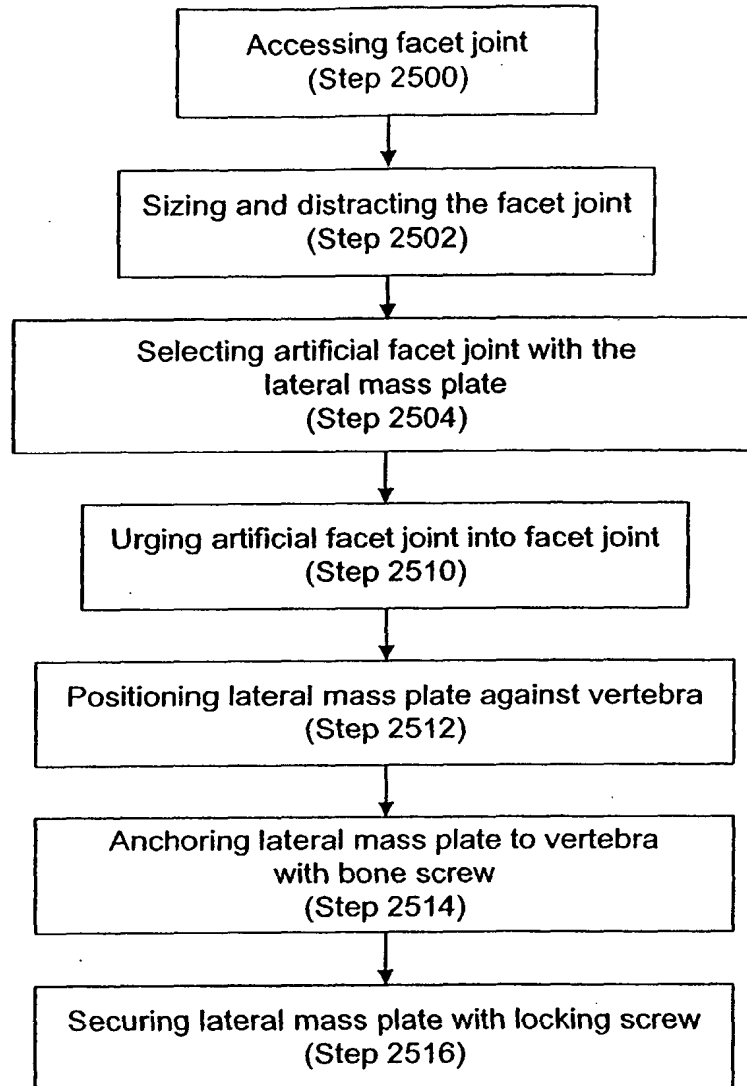


FIG. 38

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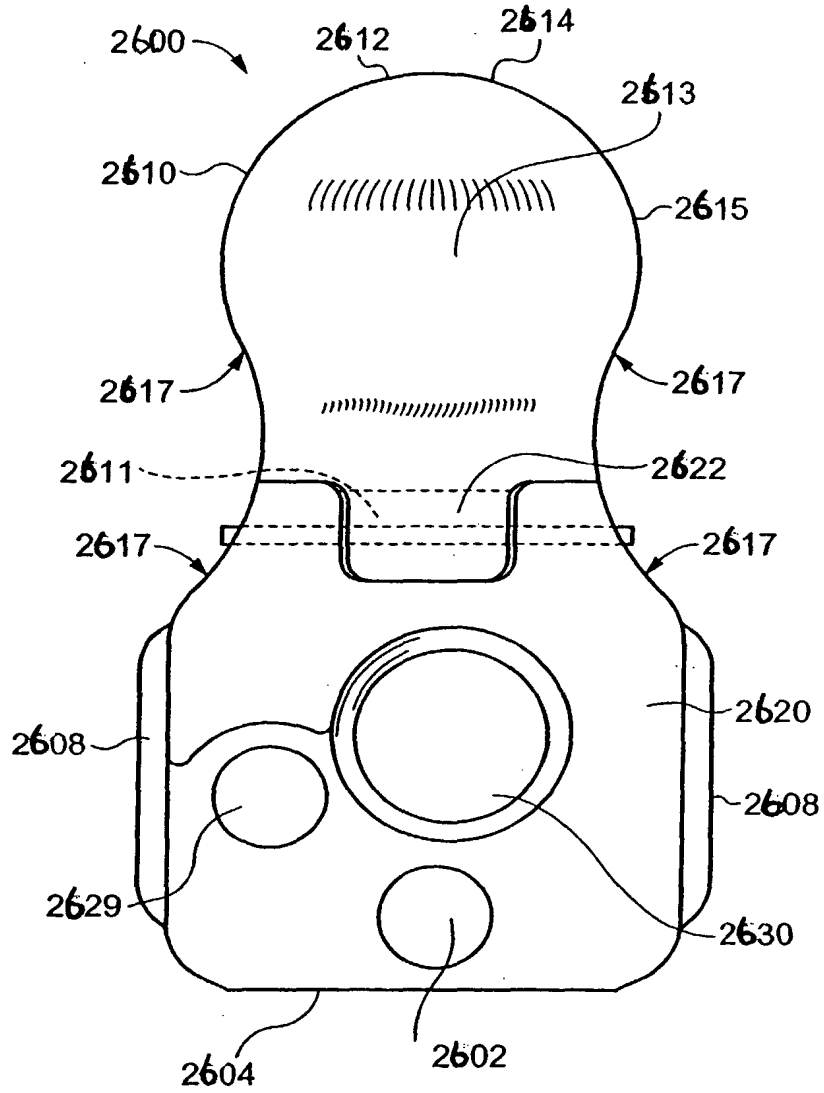


FIG. 39A

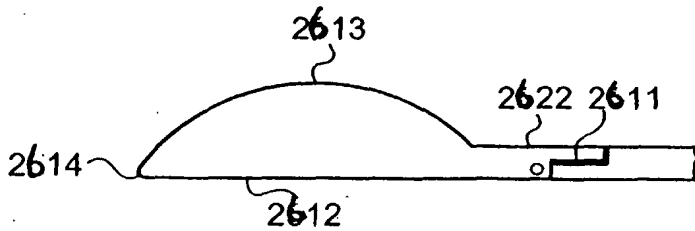
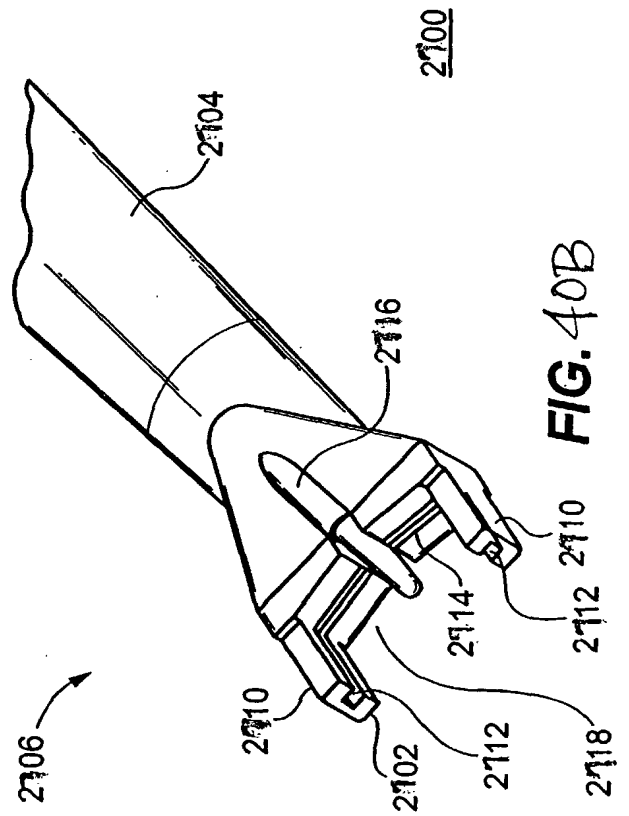
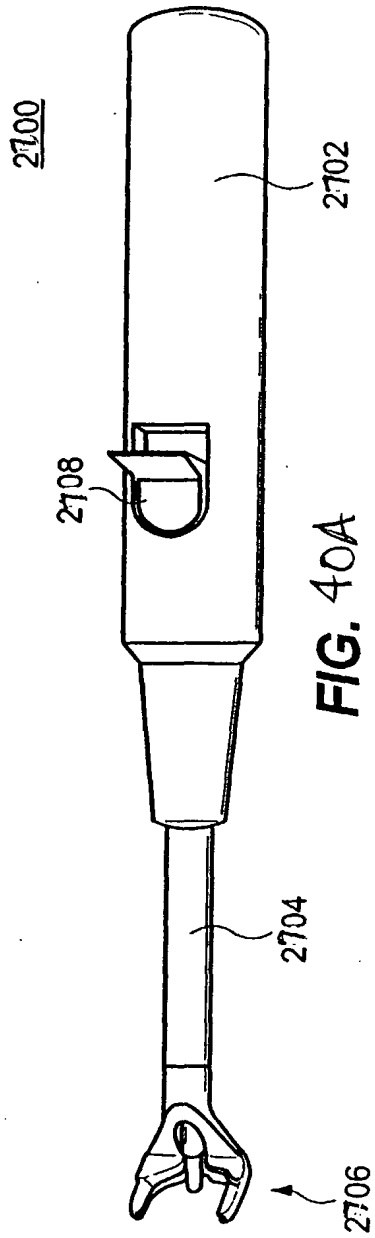


FIG. 39B



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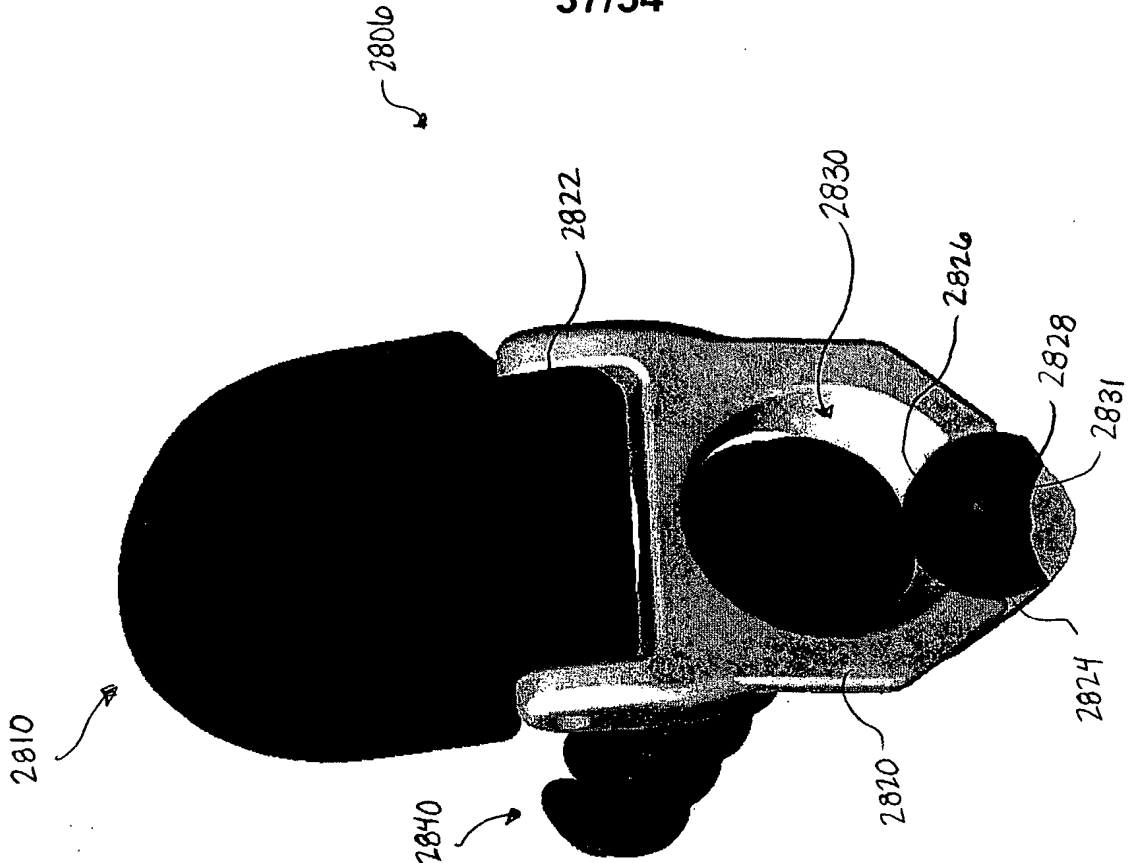


FIG. 41B

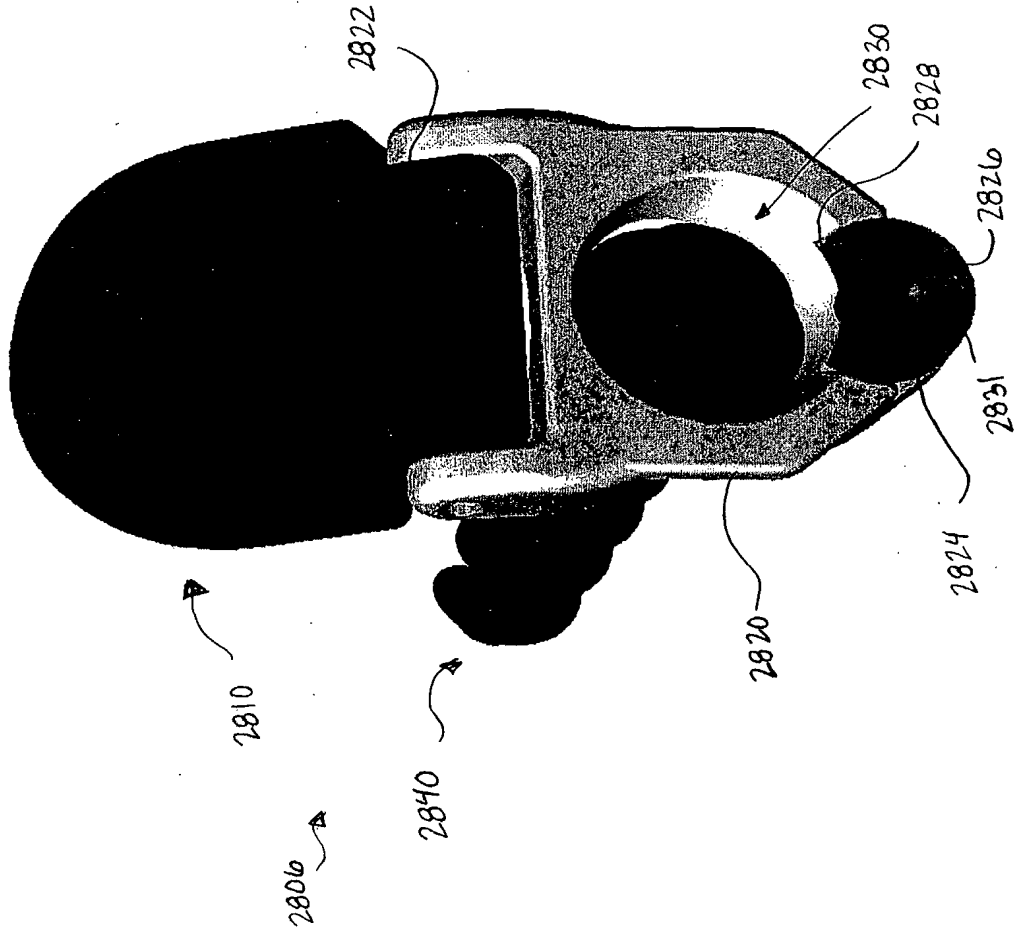


FIG. 41A

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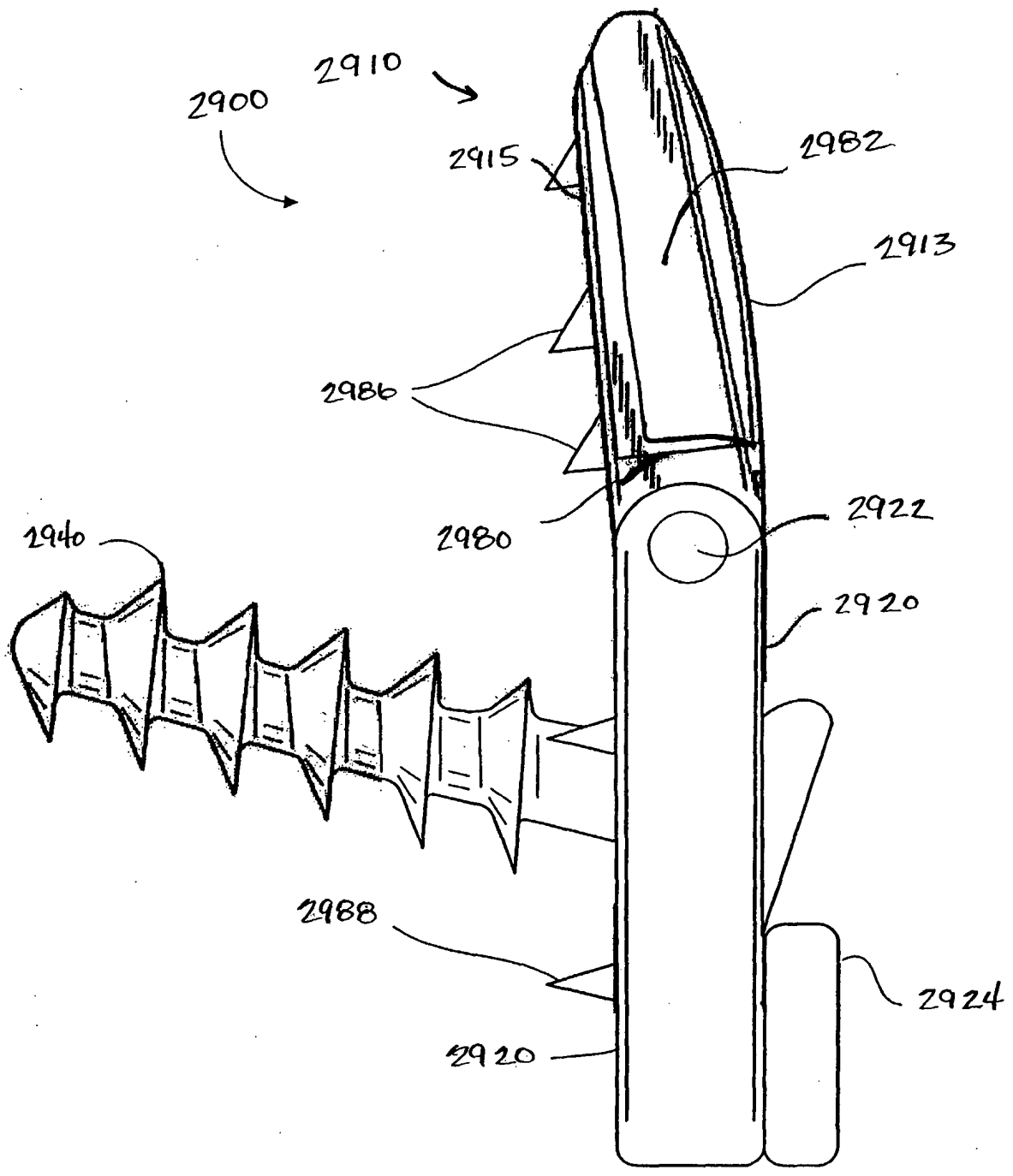


FIG. 42A

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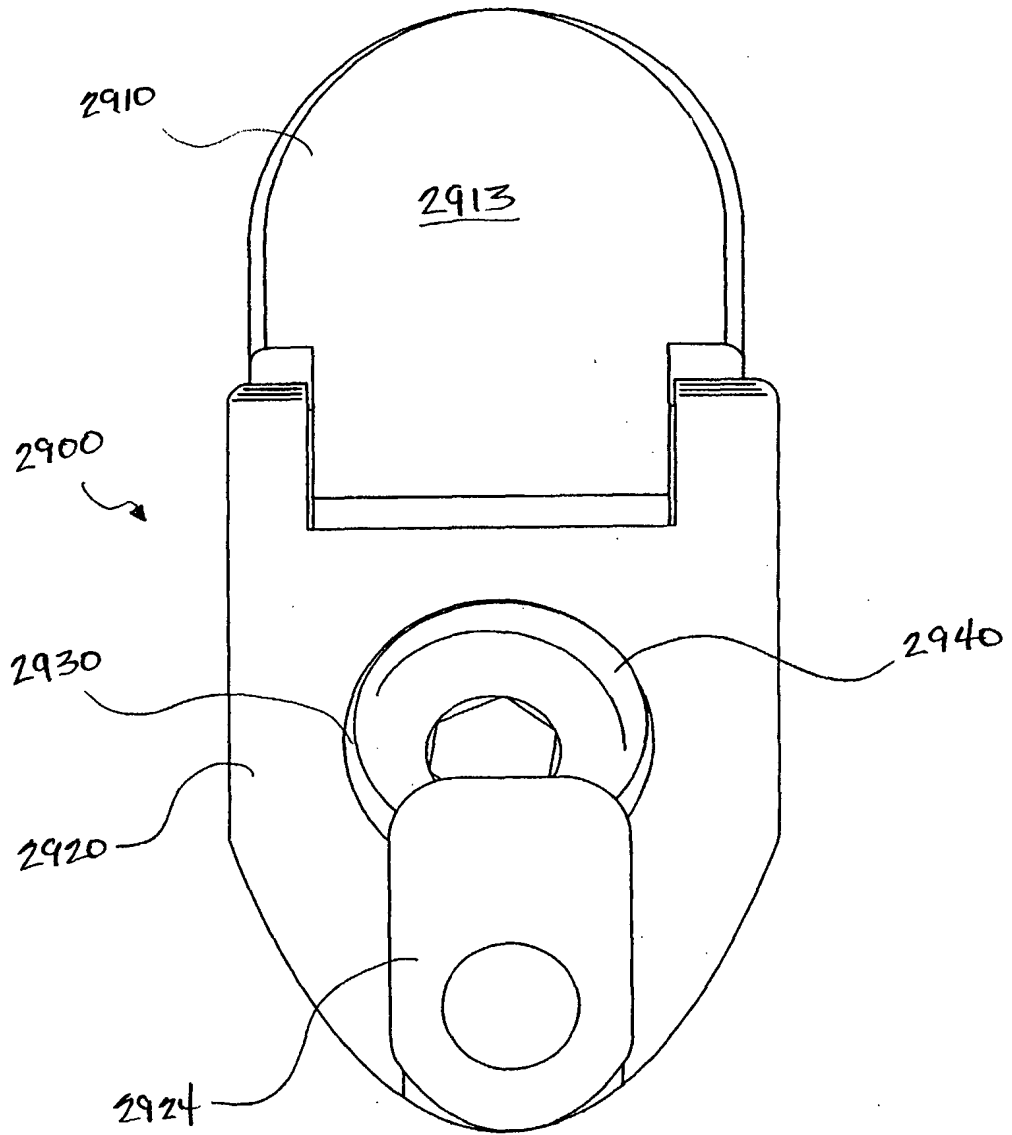


FIG. 42B

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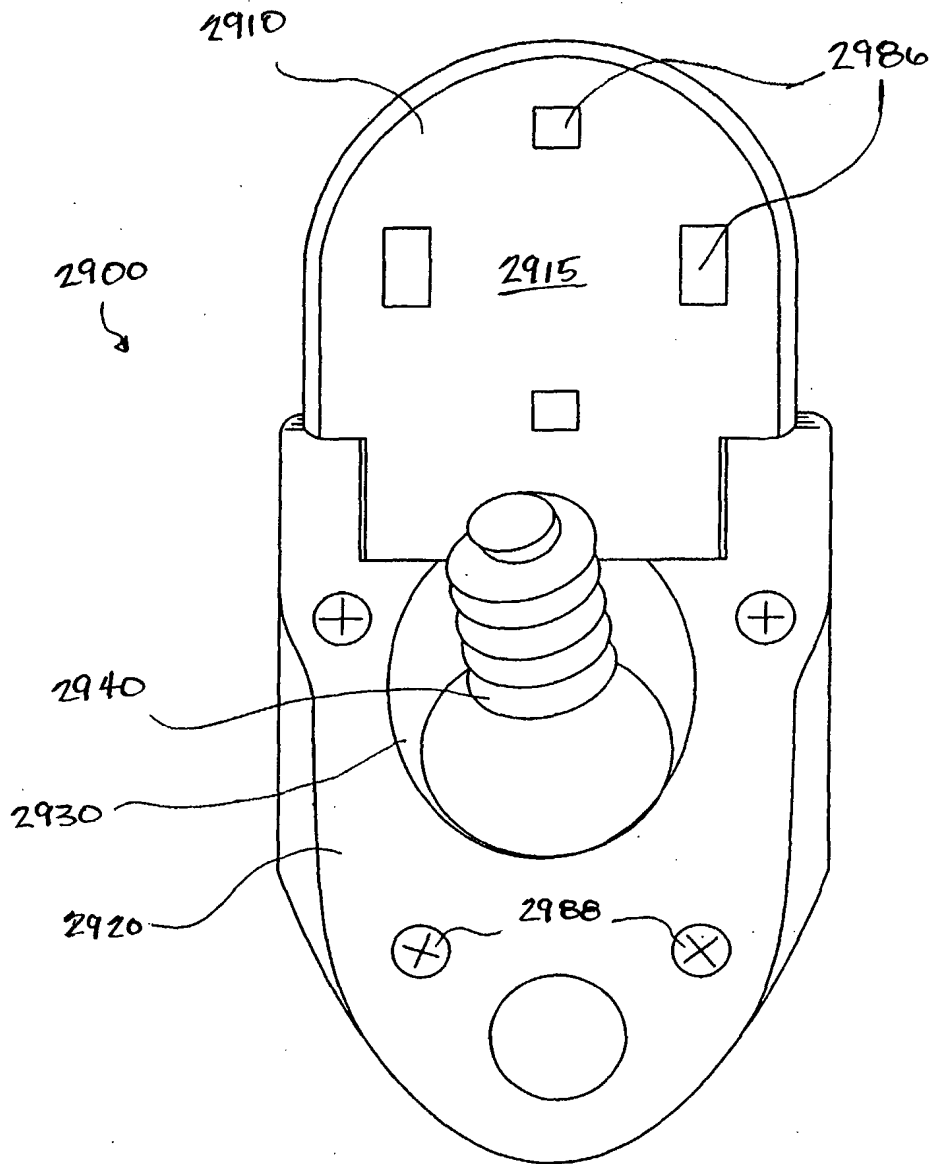


FIG. 42C

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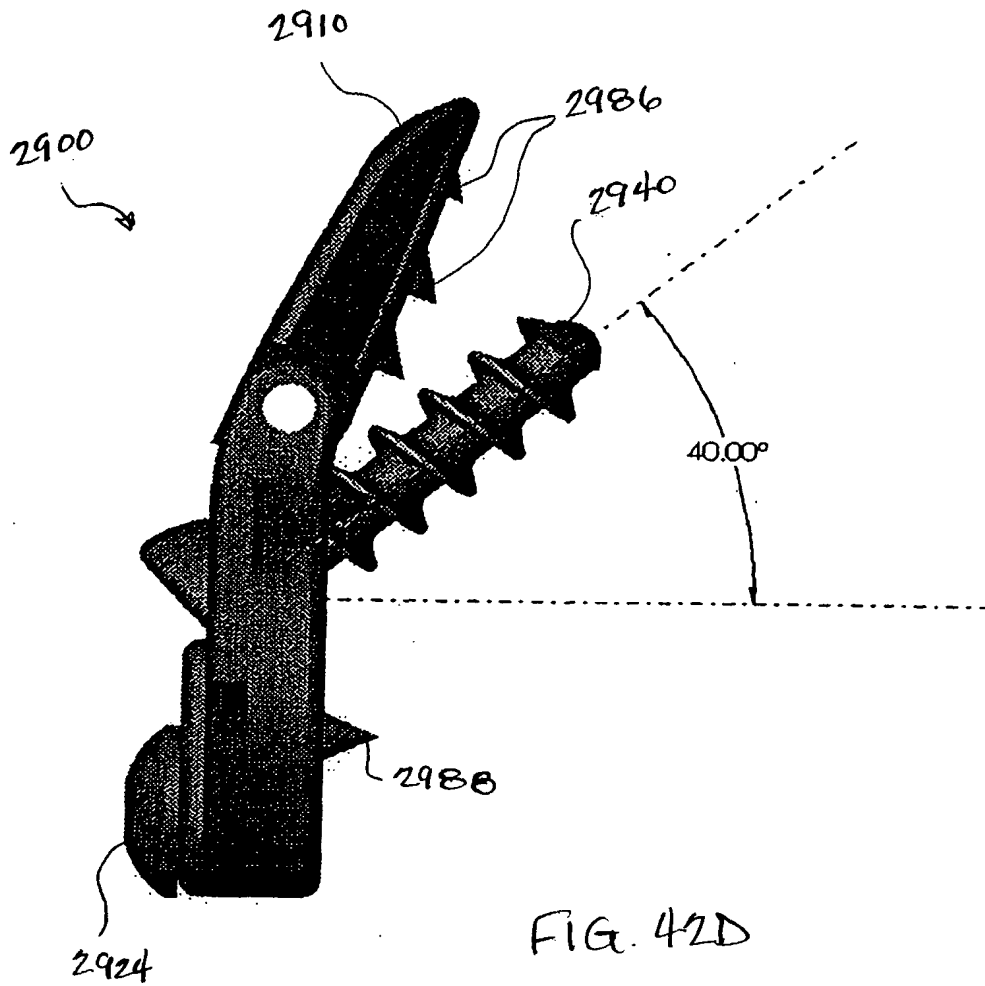


FIG. 42D

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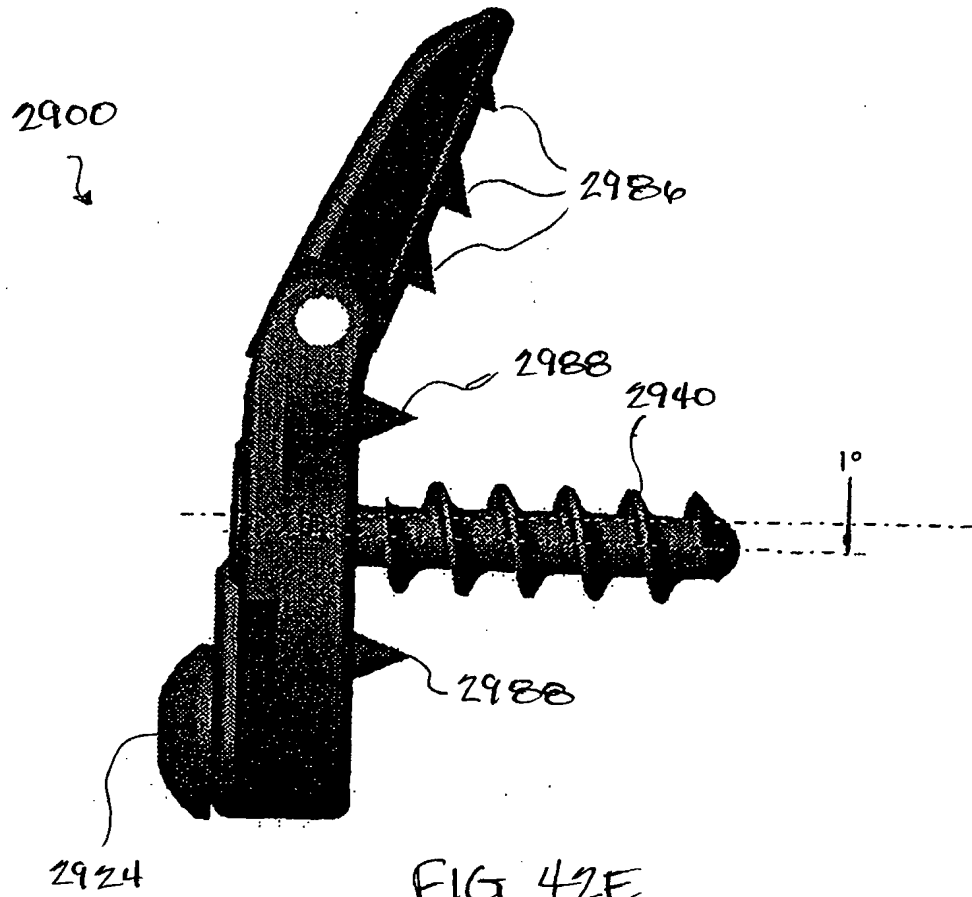


FIG. 42E

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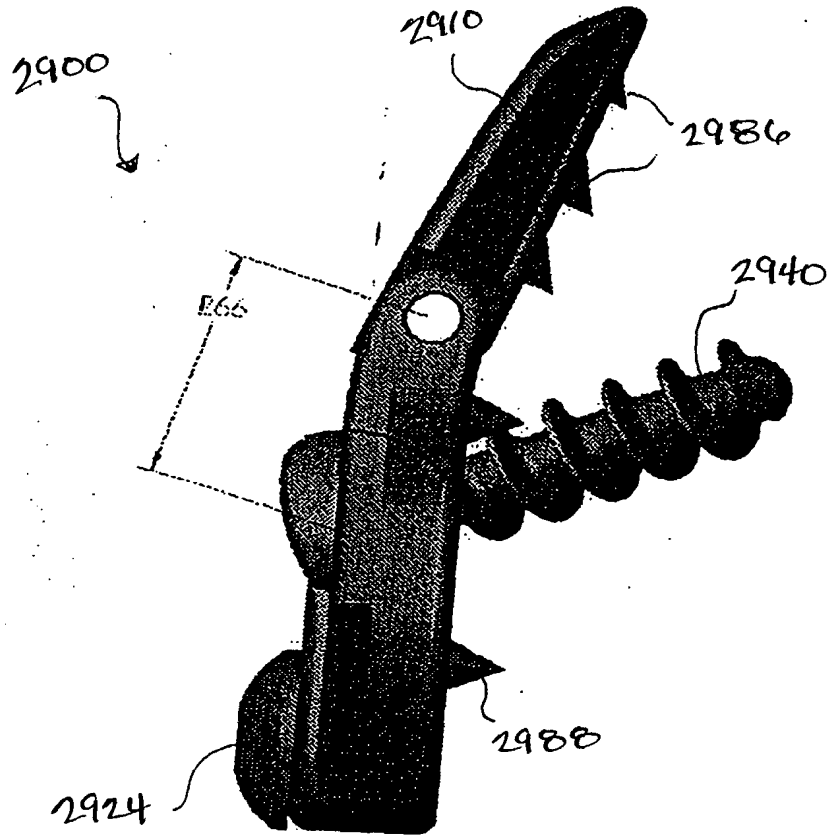


FIG. 42F

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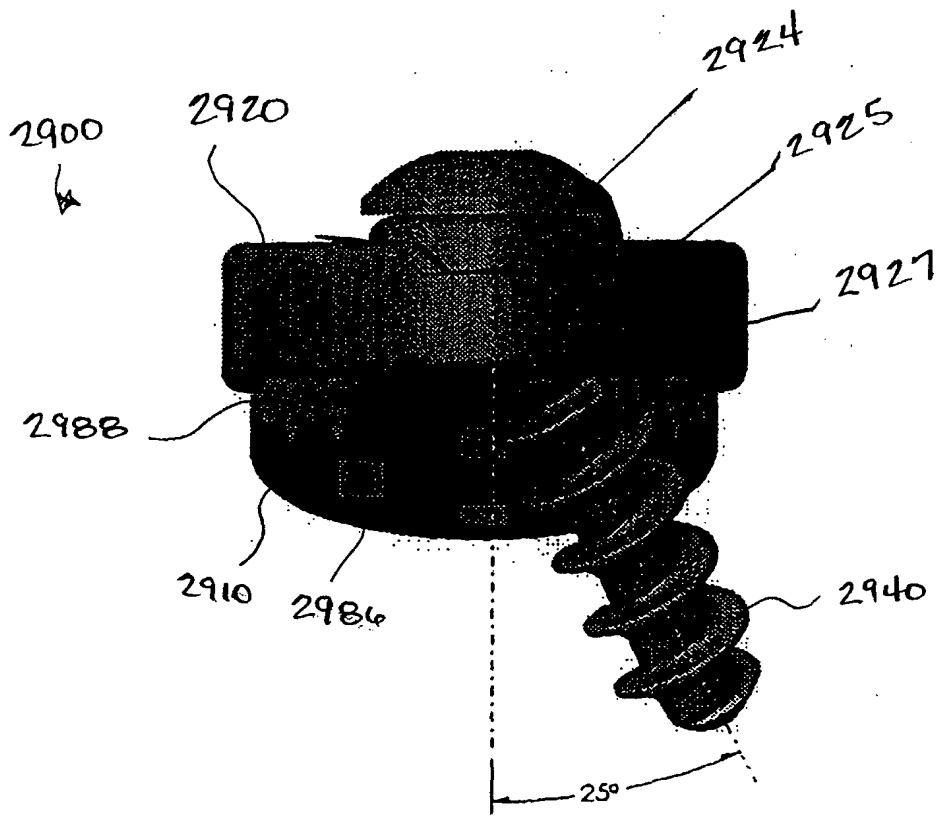


FIG. 426

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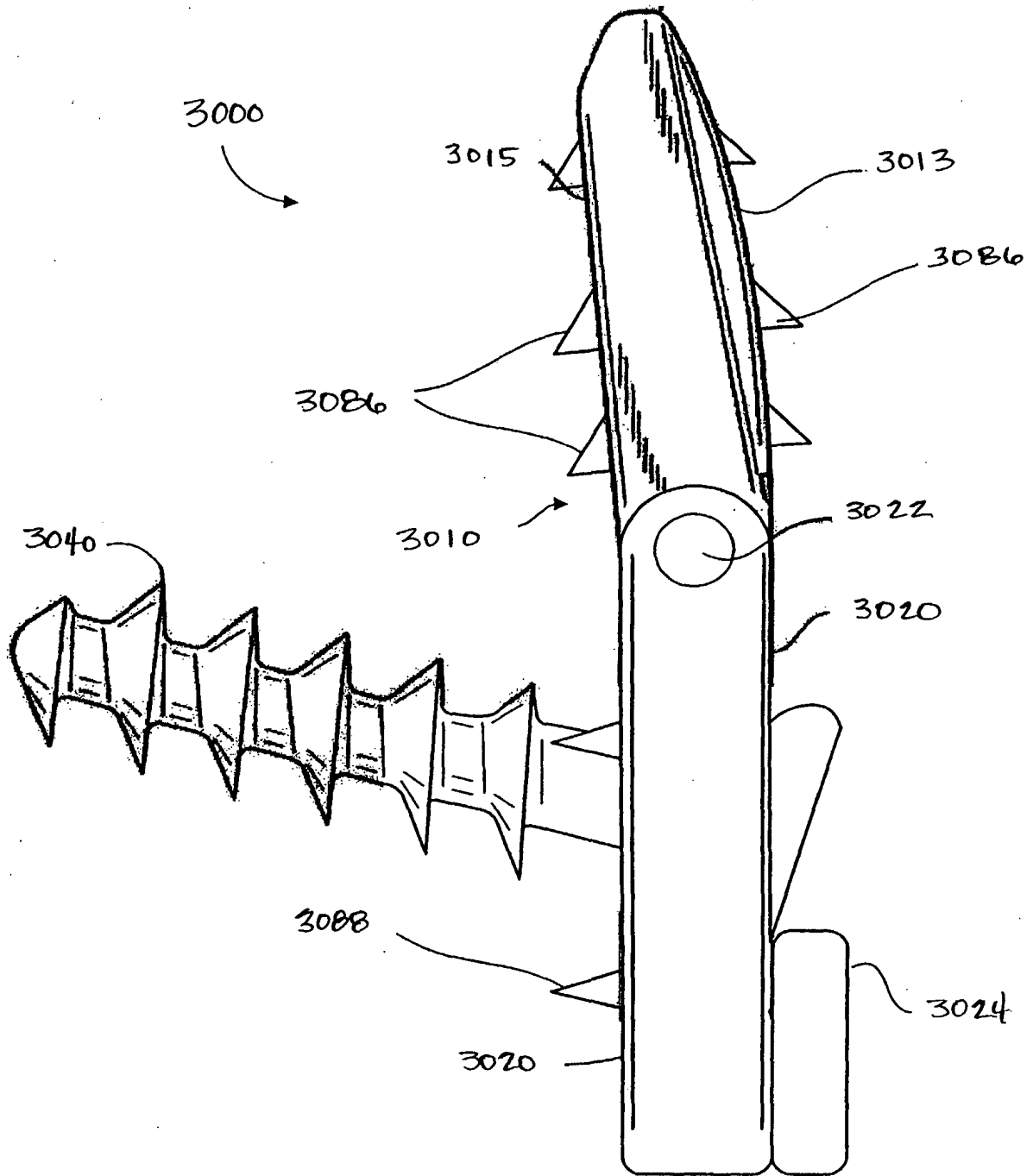


FIG. 43

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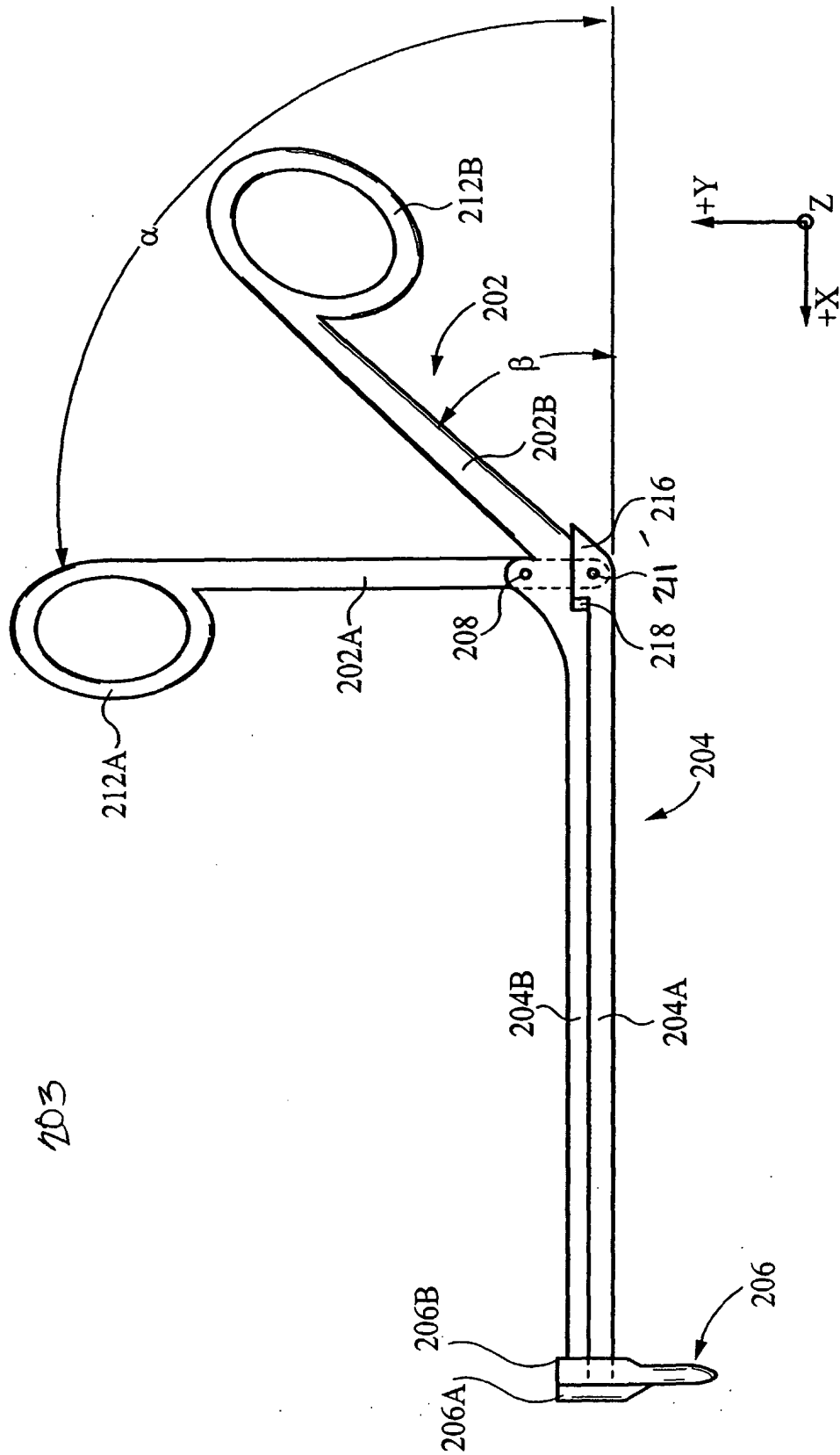


FIG. 44

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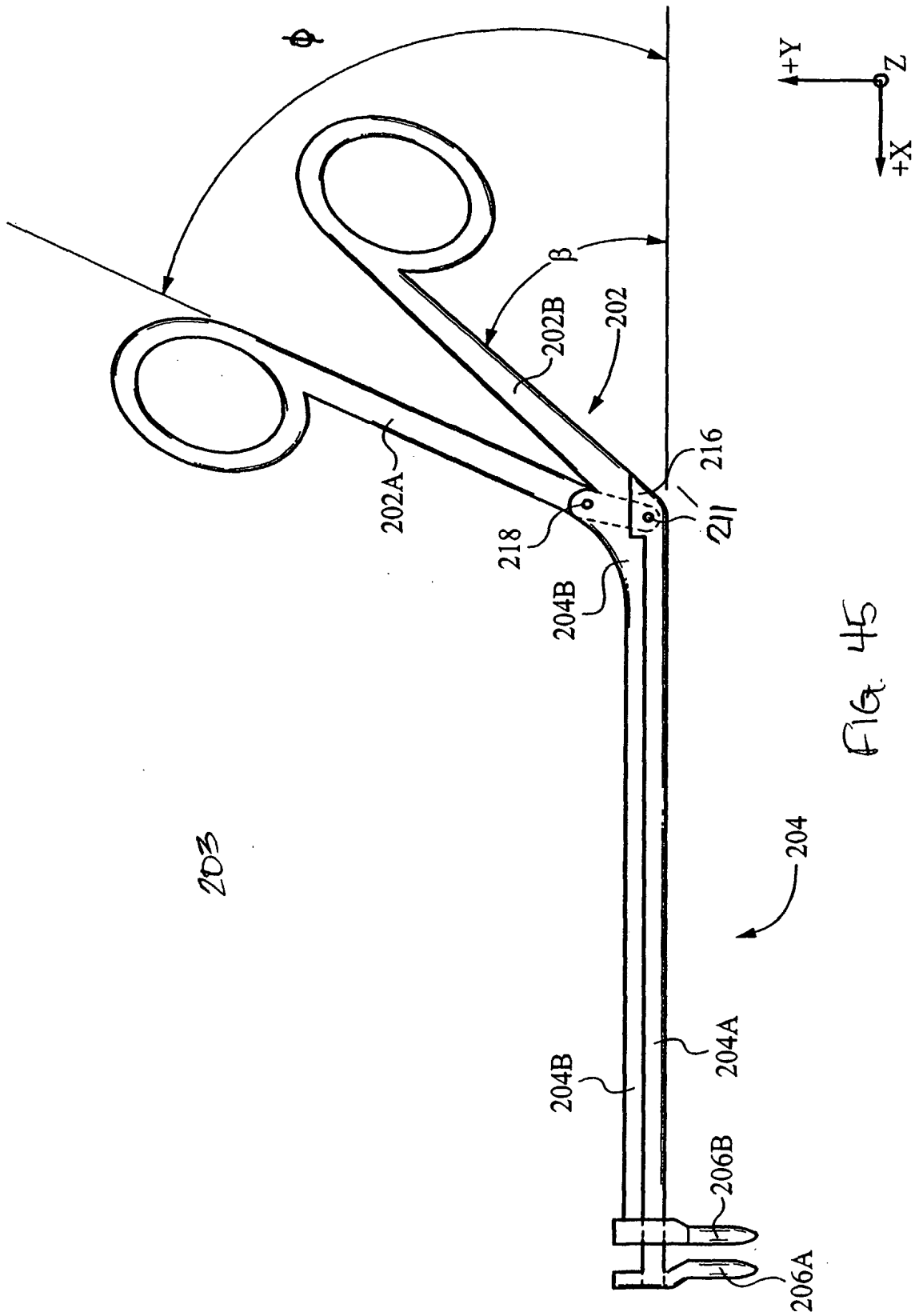
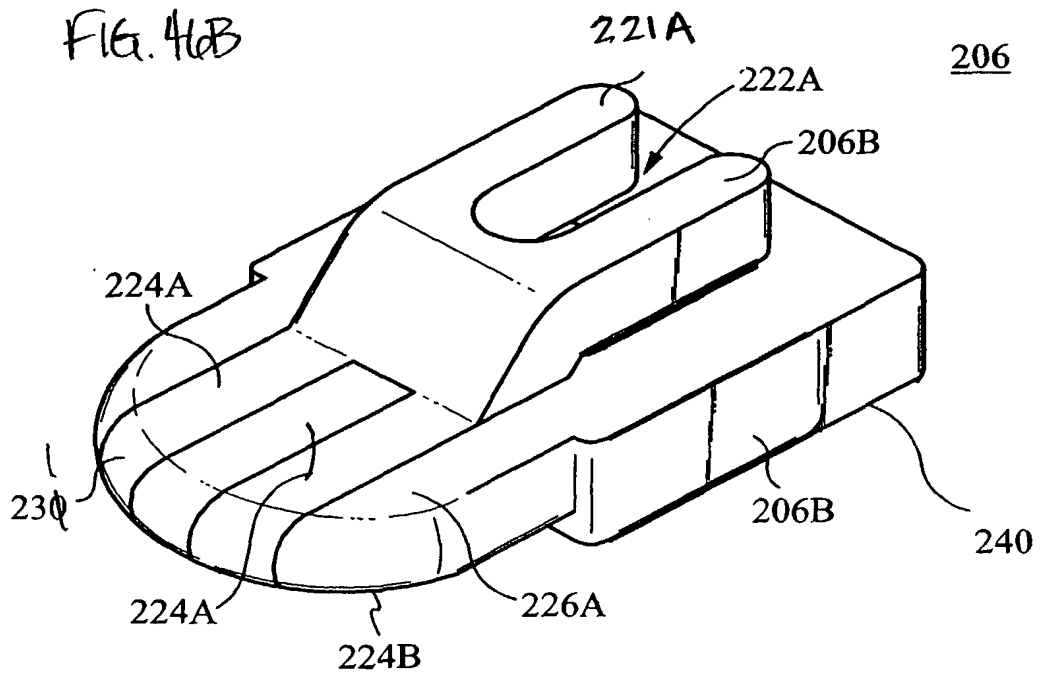
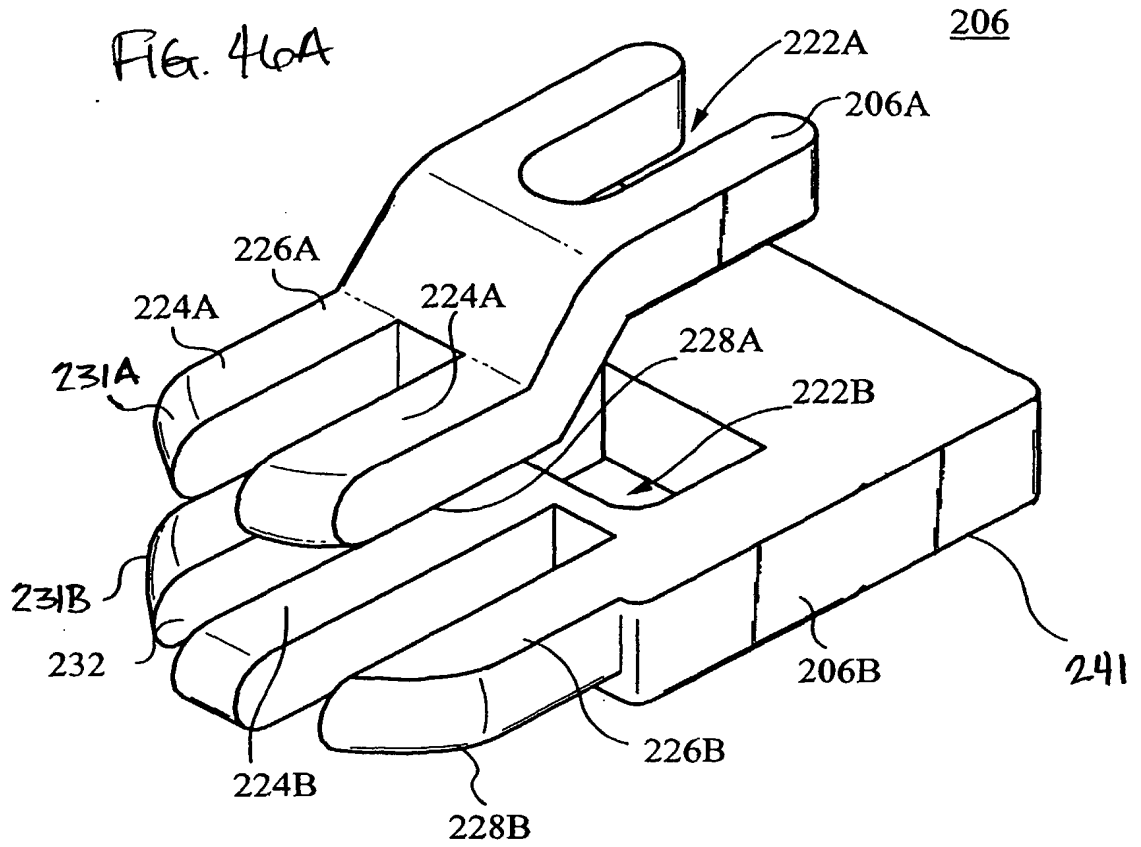


FIG. 45



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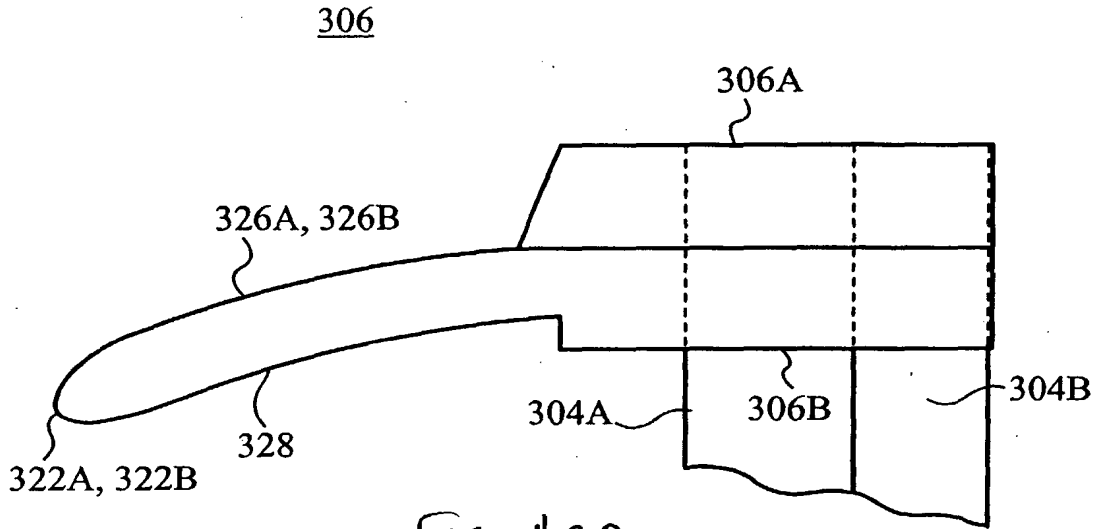


FIG. 47A

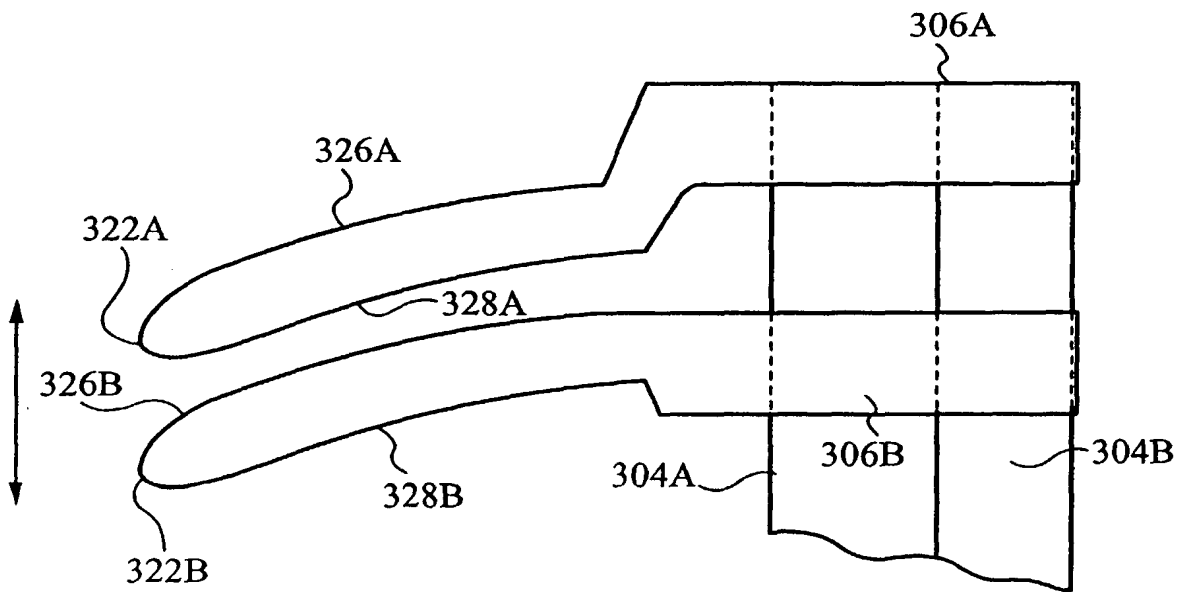
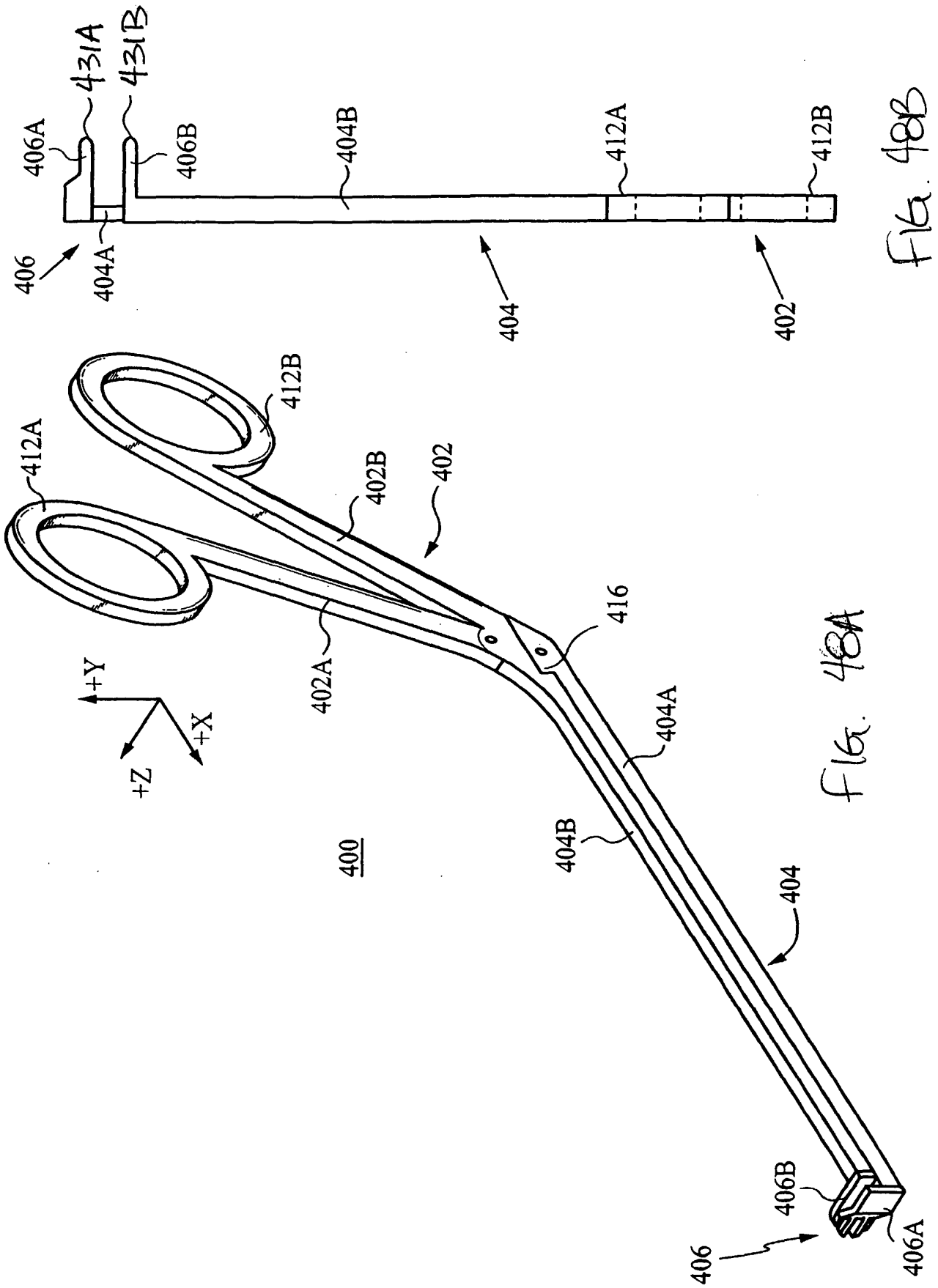
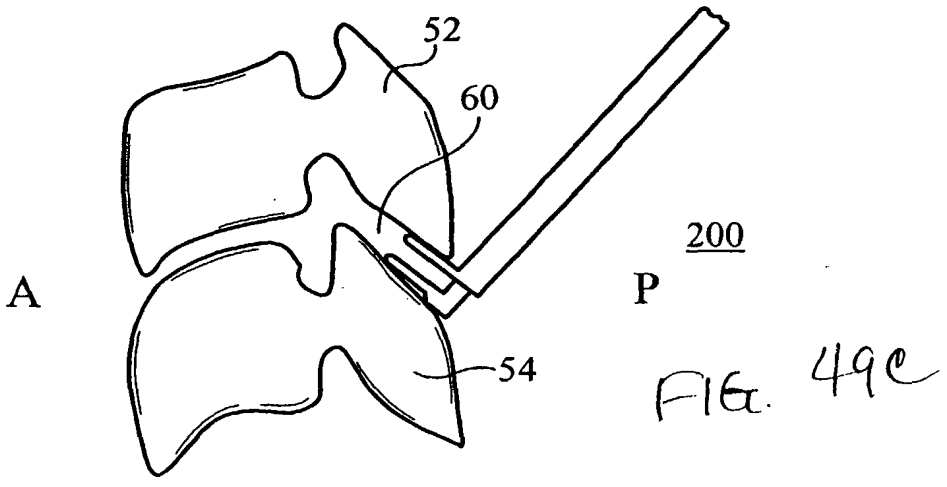
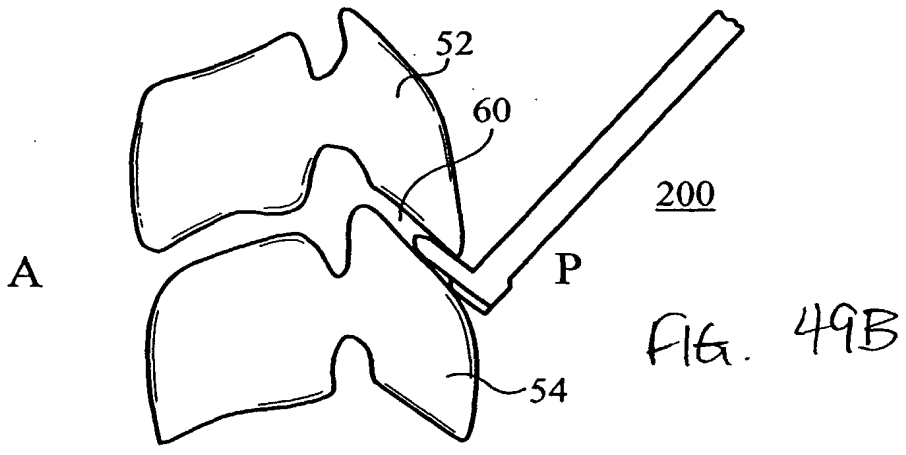
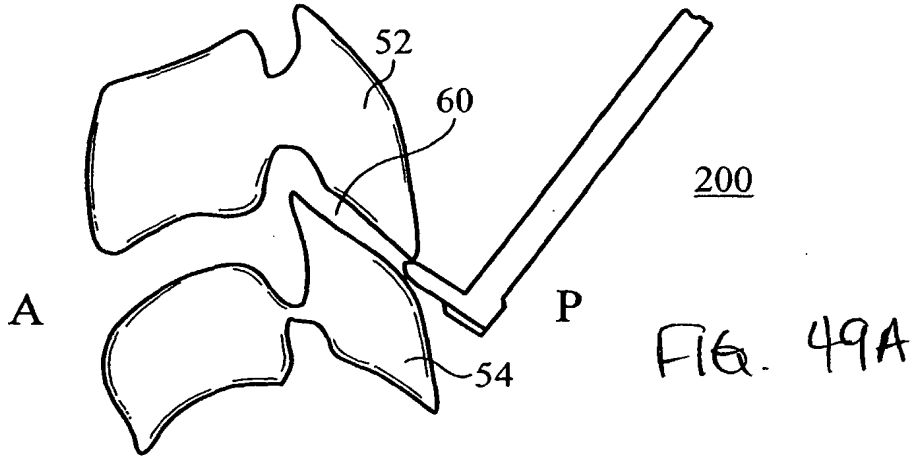


FIG. 47B



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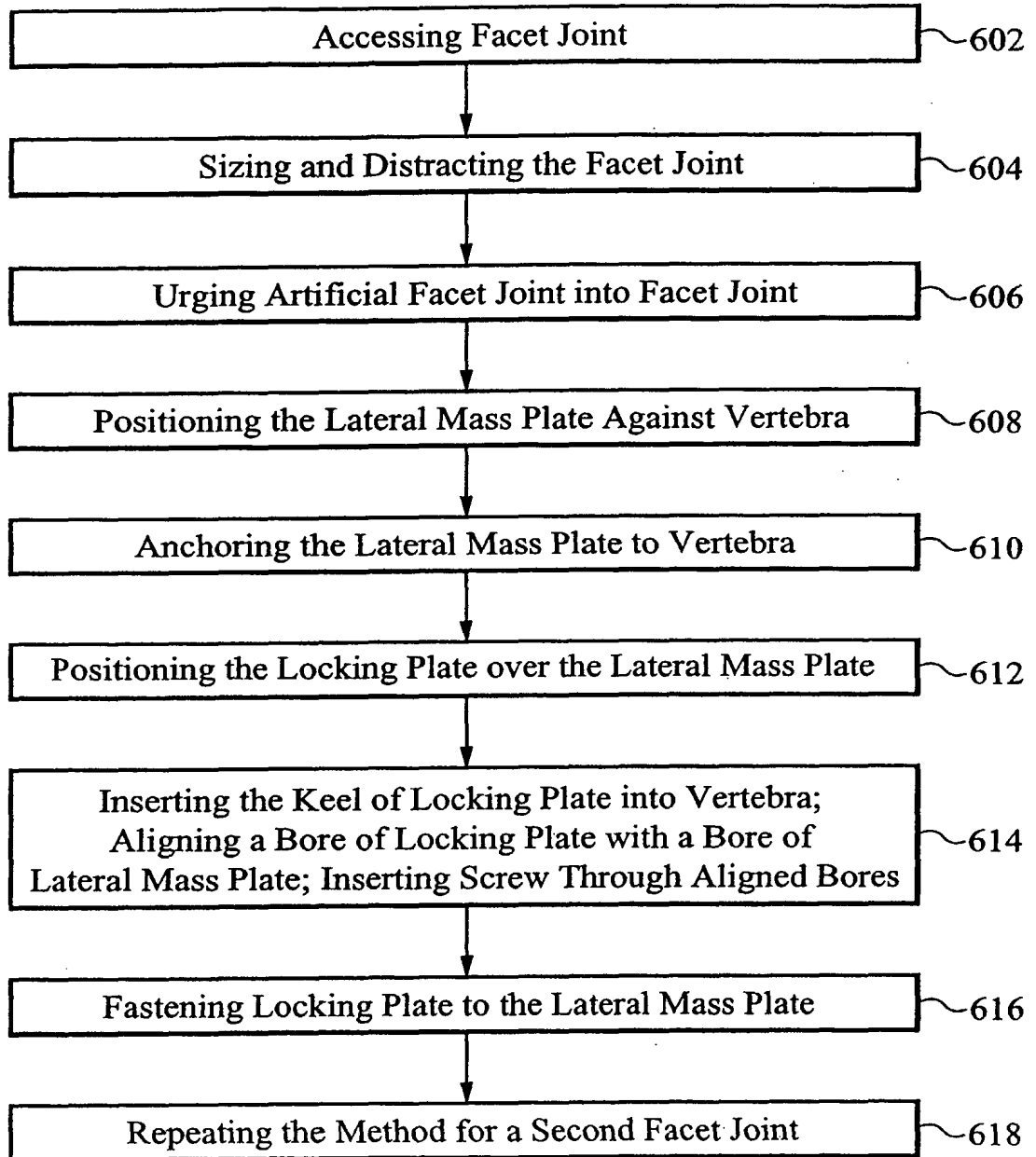


FIG. 49D

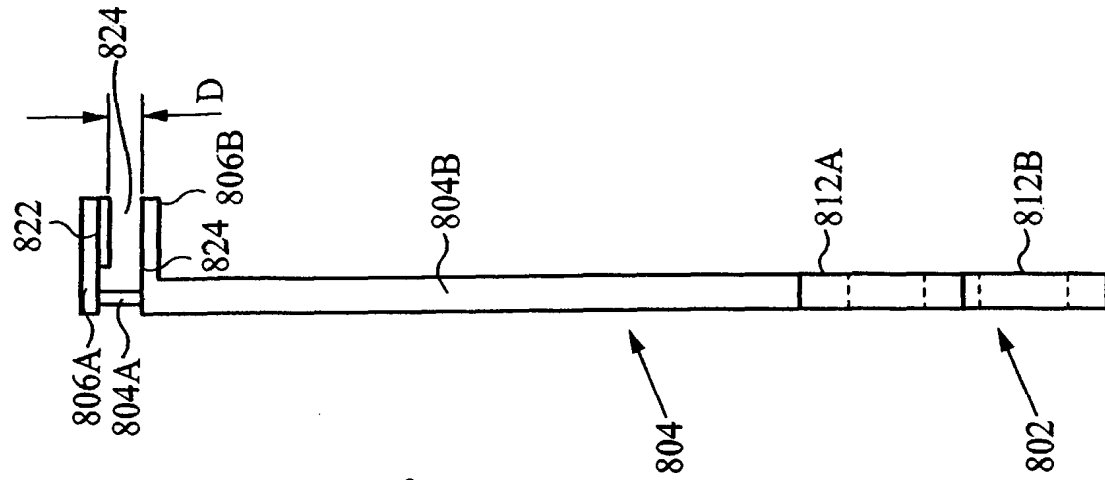


Fig. 50B

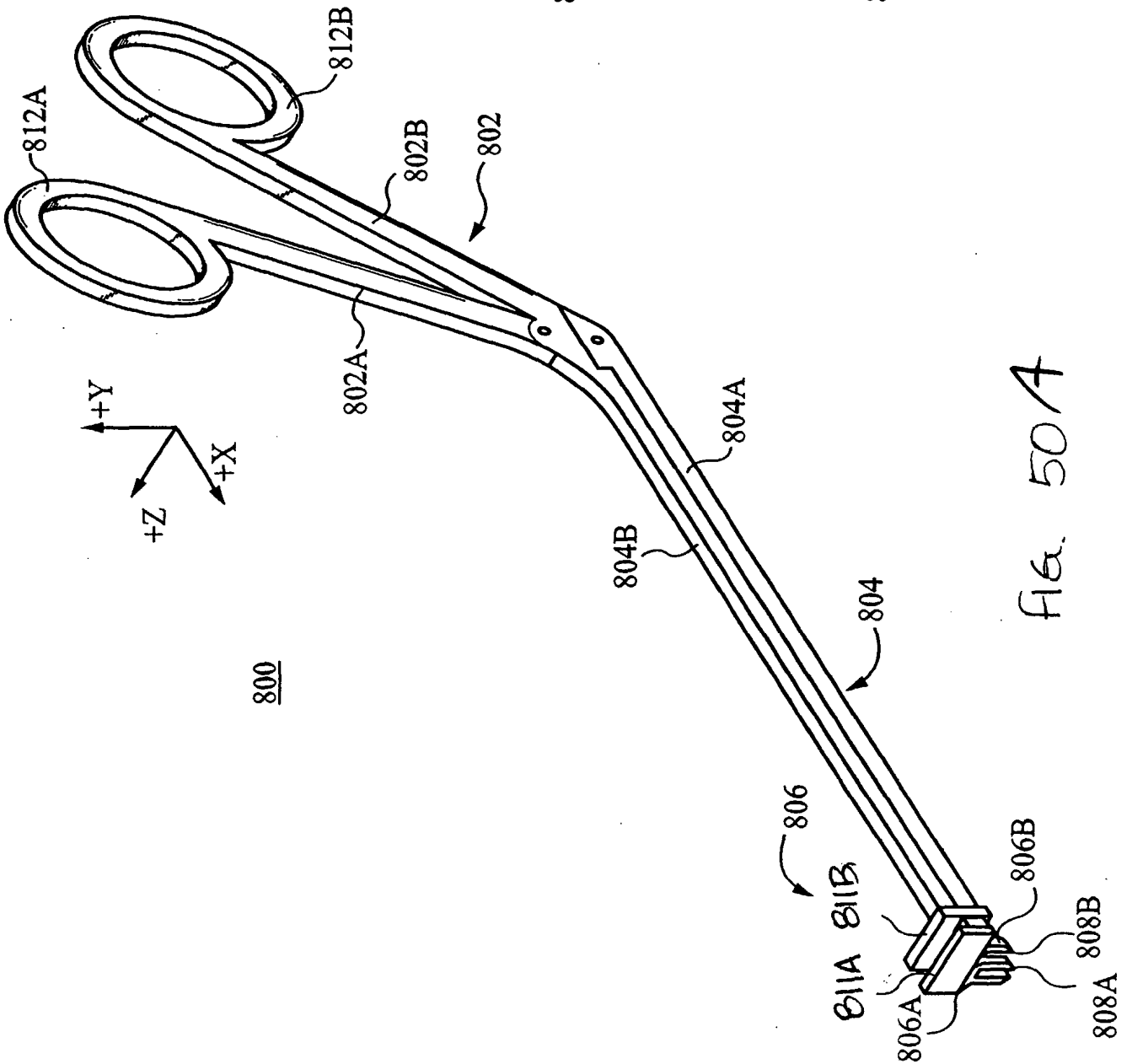
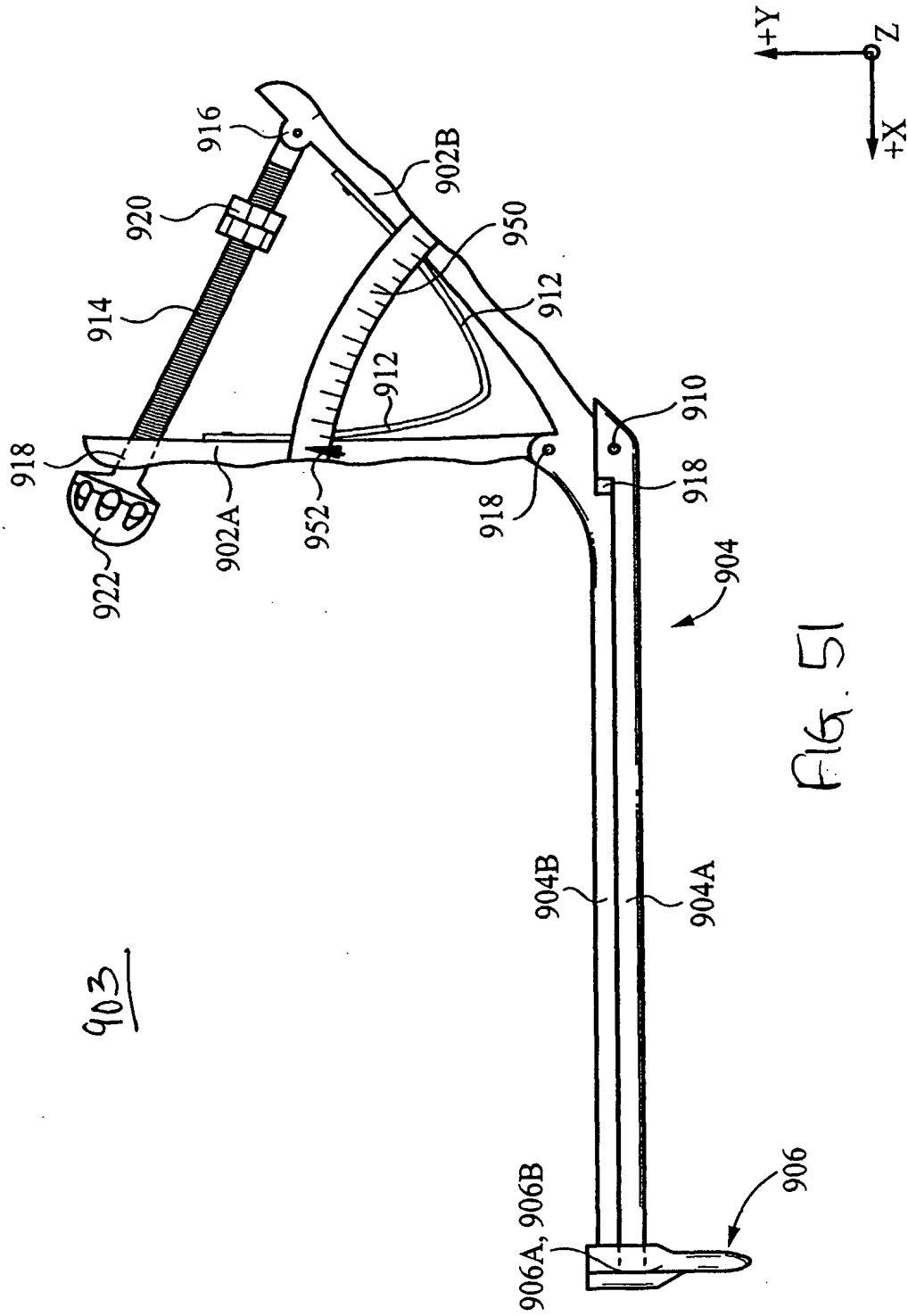


Fig. 50A



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/44979

A. CLASSIFICATION OF SUBJECT MATTER
 IPC: **A61F 2/44**(2006.01)
 A61F 2/00(2006.01),2/30(2006.01),2/32(2006.01),2/34(2006.01),2/36(2006.01),2/38(2006.01);A61B 17/56(2006.01),17/58(2006.01),17/60(2006.01)
 USPC: 623/17.11;606/61
 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
 Minimum documentation searched (classification system followed by classification symbols)
 U.S. : 623/17.11; 606/61, 90, 102, 105

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,811,567 B2 (REILEY) 02 November 2004 (02 11.2004), Figures 5 and 9, column 6, lines 37-67, columns 7-8, column 10, lines 10-67 and column 11, lines 15.	1-30, 34 and 40-54 ----- 31-33 and 35-39
X --- Y	US 6,610,091 B1 (REILEY) 26 August 2003 (26.08.2003), Figures 12-13, 41 and 42 and columns 5-10	1-30, 34 and 40-54 ----- 31-33 and 35-39
X	US 6,565,605 B2 (GOBLE et al) 20 May 2003 (20 05.2003), Figures 6-14, column 4, lines 31-67, column 5 and column 6, lines 1-19.	13-20
Y	US 6,764,491 B2 (FREY et al) 20 July 2004 (20.07.2004), Figure 9, column 5, lines 41-67 and column 6, lines 1-42.	31-33 and 35-39

Further documents are listed in the continuation of Box C. See patent family annex

* Special categories of cited documents		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	
"P"	document published prior to the international filing date but later than the priority date claimed	"&" document member of the same patent family

Date of the actual completion of the international search 29 April 2006 (29.04.2006)	Date of mailing of the international search report 31 MAY 2006
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Eduardo Robert <i>Shawn A. Greene Jr</i> Telephone No. (571) 272-4718